Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

RETRACTABLE TECHNOLOGIES, INC., and THOMAS J. SHAW	§	
	§	CIVIL ACTION NO. 2:07-cv-250
Plaintiffs,	§	(FOLSOM)
v.	§	
BECTON DICKINSON AND COMPANY,	§	JURY TRIAL DEMANDED
Defendant.	§	

AMENDED COMPLAINT

Plaintiffs Retractable Technologies, Inc. ("Retractable") and Thomas J. Shaw ("Shaw") file this action complaining of defendant Becton Dickinson and Company ("BD"), and for causes of action would show as follows:

INTRODUCTION

Defendant BD has harmed Plaintiffs, and is continuing to harm Plaintiffs, by infringing Plaintiffs' patents for safety syringes. BD has also harmed Retractable and the American public, and is continuing to harm Retractable and the American public, by falsely advertising BD's inferior, non-infringing syringe products as "safe," "safety," or "safety engineered," in order to obtain time to switch the market, at BD's own pace, to BD's infringing version of Retractable's safety syringes, which BD calls "Integra" syringes. Finally, BD has harmed Retractable and the American public, and is continuing to harm Retractable and the American public by employing unlawful exclusionary schemes to keep Retractable's technologically superior safety needle products from the market.

Plaintiffs have chosen to file this action in this Honorable Court because venue is proper in this forum and because this Court already has examined Plaintiffs' technology at issue and construed claims of two of the patents at issue in this action (the "011 Patent" and the "077 Patent"). *See* Memorandum Opinion in *Retractable Technologies v. New Medical Technologies*, No. 4:02-CV-34 (LED). BD has copied and infringed Plaintiffs' patented technology that this Court examined in *New Medical Technologies*.

NATURE OF THIS ACTION

1. Plaintiffs' patented safety syringe technology virtually eliminates the risk of needlestick injuries to healthcare workers. Needlestick injuries can transmit to healthcare workers potentially deadly diseases such as hepatitis B, hepatitis C, and Human Immunodeficiency Virus ("HIV"), the virus that causes AIDS. The American Nurses Association estimates that more than 600,000 contaminated needlestick injuries are reported each year in the United States. (*See* www.nursingworld.org/readroom/fsneedle.htm.)

2. BD is the nation's dominant maker and seller of disposable syringes and other needle products. BD is using a combination of intentional, unlawful methods, including patent infringement, false advertising, unfair competition, and exclusionary monopolistic behavior, to suppress Retractable's success in the market while BD phases new products into the market that copy Retractable's technology and infringe Plaintiffs' patents. BD is now introducing its infringing new products into the market at a controlled pace that enables BD to continue to extract maximum profits from BD's existing, but obsolete and dangerous, needle product technologies. By its unlawful conduct, BD has denied, and continues to deny, American healthcare workers access to Retractable's products, which are available now, and which incorporate the most innovative and effective safety technology available.

3. Plaintiffs file this action seeking judicial relief to terminate BD's unlawful conduct. If unchecked, BD will continue to infringe Plaintiffs' patents, deceive the market through false advertising about its own products, and engage in unfair competition and unlawful monopolistic, exclusionary conduct. BD's conduct is greatly and irreparably damaging Plaintiffs and at the same time denying American healthcare workers and patients the immediate benefits of Retractable's superior safety needle products.

4. Plaintiffs seek all relief the law allows for patent infringement. For all other claims, Retractable seeks injunctive relief and damages accruing after July 2, 2004.

PARTIES

5. Plaintiff Retractable is a Texas corporation with its principal place of business in Little Elm, Texas, within the Eastern District of Texas. Retractable is a publicly-traded company that employs approximately 150 persons within this District.

6. Plaintiff Shaw is an individual residing in Frisco, Collin County, Texas, which is also within the Eastern District of Texas.

7. Defendant BD is a New Jersey corporation with its principal place of business in Franklin Lakes, New Jersey. BD has already been served with process in this action and has appeared through its counsel of record.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under the patent laws set forth in Title 35 of the United States Code and in Title 28 of the United States Code, particularly 28 U.S.C. §§ 1331 and 1338(a); Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); the Sherman Act, 15 U.S.C. §§ 1 *et seq*.; Sections 3, 4 and 16 of the Clayton Act, 15 U.S.C. §§ 14, 15 and 26; and 28 U.S.C. §§ 1331 and 1337. This Court has supplemental jurisdiction over Retractable's state law claims pursuant to 28 U.S.C. § 1367 because they are so related to and intertwined with

Retractable's federal claims as to form a part of the same case or controversy. In addition, this Court has jurisdiction under 28 U.S.C. § 1332(a) because this action is between citizens of different states and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

9. This Court has personal jurisdiction over BD because of BD's numerous and extensive contacts with the Eastern District of Texas. BD holds a certificate of authority to transact business in Texas and regularly transacts business within Texas and the Eastern District of Texas.

10. BD has marketed and continues to market its infringing "Integra" 1 cc and 3 cc syringes within Texas and the Eastern District of Texas.

11. BD's commercial activities carried on in Texas and elsewhere throughout the United States have had a substantial, direct and reasonably foreseeable effect on business and commerce in the Eastern District of Texas and on interstate commerce.

12. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c), 28 U.S.C. § 1400(b), and 15 U.S.C. § 22.

BACKGROUND FACTS

Retractable's Patented Safety Syringes.

13. Retractable markets patented safety syringes under the name "VanishPoint®." VanishPoint® syringes are covered by a number of patents, including United States Patent Nos. 5,578,011, 5,632,733, and 6,090,077 (the '011, '733, and '077 Patents), the patents-in-suit. VanishPoint® syringes protect against needlestick injuries. VanishPoint® syringes automatically and permanently retract their needle after an injection is given and before the needle is withdrawn from the patient. Consequently, VanishPoint® syringes require no extra action by a healthcare worker to trigger their safety feature after the needle is withdrawn from a patient.

Retractable and its VanishPoint® products have been reported favorably in major news features, including in the *New York Times* and on CBS' *60 Minutes*.

14. VanishPoint® syringes have been recognized as superior safety products. For one example, in 1999 and thereafter the Emergency Care Research Institute ("ECRI"), a respected testing and evaluation service, has awarded VanishPoint® syringes its highest rating and listed them as preferred devices. (*HEALTH DEVICES*, August 2007, Vol. 36, No. 8, at p. 266.)

BD's Inferior Alleged "Safety" Syringes Render BD Competitively Vulnerable.

15. In contrast to Retractable's superior safety products introduced in the mid- to late-1990's, BD lacked innovative technology in the field of safety syringes. At the same time, the healthcare market demand for safety syringes was increasing dramatically. BD understood its vulnerability to Retractable. In order to protect its position, BD began to take unlawful actions to copy Plaintiffs' patented technology, prevent and suppress Retractable's sales, and defend, maintain, and extend its dominance in the needle product markets. Such unlawful actions by BD continue to the present day.

16. The legal environment for needle products began to rapidly change in 1999. On July 1, 1999, California's Needle Safety Law became effective. The Texas act became effective September 1, 1999. *See* TEX. HEALTH & SAFETY CODE §§ 81.301, *et seq.* On November 5, 1999, OSHA issued its Directive for Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens. On November 6, 2001, the federal Needlestick Safety and Prevention Act, P.L. 106-430 ("Needlestick Prevention Act") became law. The Needlestick Prevention Act requires healthcare employers to track needlestick injuries and to involve healthcare workers in selecting safer needle products. Since 1999, several other states also have enacted statutes to prevent needlestick injuries to healthcare workers. Beginning in 2001, OSHA regulations codified at 29 C.F.R. § 1910.1030 have required hospitals and other medical facilities to track

and report needlestick incidents and to involve front line healthcare workers in annual reviews of safety programs and needle devices. The OSHA regulations also require hospitals to employ "engineering controls," defined to include "self-sheathing needles and safer medical devices such as sharps with engineered sharps injury protections," and to evaluate the available needle products on the market and to select and use products that are effective in preventing needlesticks.

17. As a result of these statutes and the growing awareness of the needlestick problem, the healthcare industry needed and began to demand "safety" needle products.

18. Even though BD began to market product lines of needle products as "safe," "safety," or "safety-engineered," those products were not safe. Rather, BD's first alleged "safety" products incorporate nothing more than ineffective add-ons to BD's conventional disposable syringe products. BD's first alleged "safety" products are no safer than conventional syringes. In some ways, they are even more dangerous because they require a nurse or other healthcare worker to place a second hand in contact with the syringe after the needle is extracted from the patient to activate the alleged "safety" feature.

19. BD's first generation alleged "safety" syringe was the "Safety-Lok." The Safety-Lok contains an outer sleeve that a user must slide over the needle after an injection is complete and the needle is withdrawn from the patient. To operate this mechanism a user must use both hands, one to hold the syringe and the other to slide the sleeve from its position around the barrel to its extended position over the needle. This places the user's free hand at an increased risk of contacting the exposed, contaminated needle. BD's Safety-Lok mechanism is not automatic. It requires a user to actively cover the needle of the syringe. If a user takes no action, the needle remains exposed and the syringe is more bulky, harder to manipulate and no safer than a

conventional syringe. It also requires more space in a sharps container, increasing costs and risks of disposal.

20. BD's second generation alleged "safety" syringe was the "SafetyGlide." The SafetyGlide incorporates a small hinged lever between the base of the needle and the pointed tip that, when pressed forward, extends a cover over the needle tip. Activation can only occur after the contaminated needle is removed from the patient. Like the Safety-Lok, a nurse or doctor must, after injecting a patient, reach down to the syringe to engage the lever. This action again places the user's hand in close proximity to the contaminated needle, thereby increasing the risk of a needlestick injury. Like the earlier Safety-Lok, BD's SafetyGlide requires a user to take an additional physical action to press the hinged lever before the safety device engages. There have been reports that the safety feature on these earlier generation BD products from time to time would simply fall off the syringe, thereby exposing the contaminated needle. (*CBS 60 Minutes,* broadcast Feb. 25, 2001.)

21. Another alleged "safety" syringe marketed by BD is the "Eclipse," which features a hinged shield at the base of the needle that can be pivoted to cover the needle. After injecting a patient, a user must withdraw the needle from the patient, reach down to the exposed, contaminated needle, and flip the Eclipse shield into place by hand or place the syringe with its exposed needle on a table-top or other firm surface against which the shield can be flipped into place. Flipping the shield into place also can throw blood and/or aerosolized fluids from the needle and onto healthcare providers, patients, or surrounding surfaces.

22. As the healthcare industry began to comply with the Needlestick Prevention Act, OSHA requirements, and state needlestick safety laws, BD needed to accelerate the conversion of its product line from conventional to safety syringes. At the same time, BD began to take a

series of actions to protect its dominant market positions in needle products from Retractable's innovative, patented technology.

23. BD was unable to replace its inferior "safety" product line overnight. Nor did it want to do so when it was reaping substantial profits from the stop-gap alleged "safety" products that used parts from already-existing manufacturing facilities and tools. Instead, BD, misusing its power in the markets, continued to market its inferior alleged "safety" products to the American public.

BD'S UNLAWFUL ACTS

Patent Infringement.

24. Upon information and belief, BD copied Retractable's syringes during the course of developing BD's fourth generation of so-called "safety" syringe, the Integra. During a 2001 interview, the CEO of BD admitted that BD was not the first to invent many of its products and that "we're just good adapters." (Philip Siekman, *Becton Dickinson Takes a Plunge With Safer Needles; By Gearing Up to Make Devices Like These the Company is Giving its Profits a Shot in the Arm*, *FORTUNE* (October 2001) at 2 (Lexis print).)

25. Once BD had made a syringe incorporating much of the technology disclosed in Retractable's syringes and patents, BD unveiled the "Integra" syringe in 2003. Unlike BD's earlier alleged "safety" syringes, Integra is a retractable syringe.

26. BD's Integra syringes infringe Plaintiffs' patents. Like VanishPoint® syringes, Integra syringes have a spring loaded needle that is fired by continuing to push the plunger after the injection is complete. This releases the needle holder from a retaining ring so the needle retracts back into the syringe body. The Integra syringes also use the same "breakaway" feature for releasing the needle holder from the retainer ring that is taught in Plaintiffs' patents. The Integra 3 cc syringe has a plunger thumb cap that tucks down into the top of the syringe barrel so

that it cannot be easily pulled out and reused, and has vents to relieve air pressure from the retraction cavity and prevent splattering when the needle is retracted. These features are disclosed and claimed in Plaintiffs' patents.

27. As BD sells infringing syringes and engages in other illegal activities, Plaintiffs are losing the value of their most valuable asset, which is the remaining term of their patents. Plaintiffs' patents are assets with definite expiration dates. Once Plaintiffs' patents expire, their lost opportunity in the marketplace cannot be fully reclaimed.

28. BD's infringement of Plaintiffs' patents, together with its unlawful exclusion of Retractable from the markets, is greatly damaging both Plaintiffs and healthcare workers. Through BD's infringing manufacture and sale of its Integra products, BD can control the demand for retractable syringes that occurs when healthcare workers are made aware of the superior safety and ease of use of Plaintiffs' patented technology. BD can claim, in effect, "Oh, we have one of those retractable needles," while continuing to sell its older "safety" products on which BD maintains substantially higher profit margins. In this way, BD can maintain control of the entire needle product markets and use the Integra products as an aid to extending its profits and sales of its earlier non-retractable "safety" syringe products such as the Safety-Lok, the SafetyGlide, and the Eclipse. Hundreds of thousands of needlestick injuries, each representing possible disease or death to a healthcare worker, will continue to occur if BD's unlawful conduct continues unchecked. BD's actions have caused and will continue to cause irreparable harm to Retractable, medical personnel, and the general public.

False Advertising.

29. BD's Safety–Lok, SafetyGlide, and Eclipse products are no safer than, and can be more dangerous than, conventional needle products. At least one study has shown that the number of needlestick injuries decreased after a test group ceased using the Safety-Lok syringe

and resumed using conventional syringes. Nevertheless, BD continues to advertise the Safety–Lok, SafetyGlide, and Eclipse products as "safe," "safety," or "safety-engineered" products.

30. A recent study by an independent hospital found that needlestick injuries increased when the hospital began to use BD's alleged "safety" products in 2003. The same study showed that needlestick injuries were virtually eliminated when the hospital switched to VanishPoint® products in 2004 and 2005.

31. Public records show that most current so-called "safety" needles sold, most of which are the BD Safety-Lok, SafetyGlide, and Eclipse needles described above, are ineffective. For example, in 2004 the State of Texas received reports of 370 needlestick incidents involving so-called "safety engineered" products. In 243 of those incidents, the alleged "safety mechanism" had not even been activated (www.state.tx.us/idcu/health/bloodborne_pathogens /report/– Tables 18 and 19). Accordingly, BD's Safety-Lok, SafetyGlide, and Eclipse products are dangerous for the additional reason that the alleged "safety" features on those products are feared or not trusted by, and thus not activated by, the healthcare workers they purport to protect.

32. In connection with its Safety-Lok, SafetyGlide, and Eclipse products, BD has used in interstate commerce words, terms, names, and combinations thereof, and false and misleading descriptions and representations of fact, in commercial advertising and promotion to misrepresent the nature, characteristics, and qualities of the Safety-Lok, SafetyGlide, and Eclipse products, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). This false and misleading advertising and promotion by BD has occurred since July 2004 and continues to the present.

33. BD has long known (and publicly stated) the simple, common knowledge that the critical window for contaminated needlestick injuries is after injection or blood-drawing and

before disposal into a sharps container. If one can *eliminate* that exposure window, then one can eliminate most contaminated needlestick injuries.

34. Retractable's VanishPoint syringes eliminate that critical exposure period because the needle retracts from the patient directly into a shielded position. BD's Safety-Lok, SafetyGlide, and Eclipse cannot eliminate that exposure period because the needle covers on those devices must be manually moved into place after the needle is removed from the patient.

35. Nevertheless, both on-line and in other marketing, BD directly states or implies that use of the Safety-Lok, SafetyGlide, and Eclipse will meet the Needlestick Prevention Act's mandate to use devices that will "prevent percutaneous injuries," "be effective in eliminating or minimizing occupational exposures" to bloodborne pathogens, and be "effective in reducing occupational exposures to the lowest feasible extent."[1]

36. BD's Safety-Lok is no safer, and indeed can be more dangerous, than conventional syringes because the Safety-Lok contains an outer sleeve that a user must physically push over the exposed needle after an injection is complete. This action places the user's hand at increased risk of contacting the contaminated needle. BD nevertheless uses the words, terms, and names "safe," "safety," "safety-engineered" and similar descriptions in commercial advertising and promotion to describe the nature, characteristics, and qualities of the Safety-Lok syringe, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

37. For example, BD advertises the "BD Safety-Lok™ Sliding Sleeve Syringe" as offering "Step-by-Step Safety" and as "The World's First Safety Syringe." Boasting that "BD Safety-Lok is the best-selling safety hypodermic device on the market," BD claims that Safety-

[1] *See, e.g.,* http://www.bd.com/safety/faqs/ (BD Resource Center, "Needlestick Safety and Prevention Law Frequently Asked Questions & Answers") (accessed and printed on 7/29/2007).

Lok offers "safety injection" and will "provide safety-engineered protection."[2] These claims and similar claims have been made in interstate advertising since July 2004 to the present day.

38. BD's SafetyGlide is no safer, and indeed can be more dangerous, than conventional syringes because it has a small hinged lever at the base of the needle that, when pressed by the user, extends a cover over the needle. Consequently, after using the syringe to inject a patient and withdrawing the needle from the patent, the user must reach down to the needle and engage the lever. This action places the user's hand in close proximity to the blood-contaminated needle, thereby increasing the risk of a needlestick injury. BD nevertheless uses the words, terms, and names "safe," "safety," "safety-engineered," and similar descriptions in commercial advertising and promotion to describe the nature, characteristics, and qualities of the SafetyGlide syringe, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

39. For example, in interstate advertising since July 2004, BD has advertised its SafetyGlide as offering "Safety Without Compromise" and "Step-by-Step Safety."[3] BD also claims that "SafetyGlide is setting a new standard in safety injection."[4] These are but some of many examples of such claims made by BD since July 2004 to the present day.

40. BD's Eclipse products are no safer, and indeed can be more dangerous, than conventional products because they include a hinged shield at the base of the needle that when hit or pushed flips into place over the needle. A user must, after injecting a patient and withdrawing the needle from the patient, reach down to the needle with a hand to flip the shield

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[2] *See, e.g.,* http://www.bd.com/injection/products/pdf/BD_safetylok_syringe_brochure.pdf (on-line in July 2007 and, upon information and belief, for months before and since).

[3] *See, e.g.*, http://www.bd.com/injection/products/pdf/BD_safetyglide_needle_brochure.pdf (on-line in July 2007 and, upon information and belief, for months before and since).

[4] *See, e.g.*, http://www.bd.com/injections/products/pdf/BD_safetylok_syringe_brochure.pdf .

into place, or else move the syringe, with its exposed, blood-contaminated needle, to a table-top or other firm surface against which the hinged shield can be flipped into place. Flipping the shield into place has been observed to throw blood and/or aerosolized fluids from the needle and onto healthcare providers, patients, or surrounding surfaces, thus, increasing the risks of infection. BD nevertheless uses the words, terms, and names "safe," "safety," "safety-engineered" and similar descriptions in commercial advertising and promotion to describe the nature, characteristics, and qualities of the Eclipse syringe, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

41. For example, BD claims that Eclipse "provides safe activation" as well as "Step-by-Step Safety" and "Safety made simple."[5] BD made these and similar false or misleading claims in advertisements since July 2004.

42. Much of BD's advertising and other marketing also fails to disclose the material splatter risk of the Eclipse.[6] BD clearly understands the importance of that risk, since it has, in the past, warned of splatter risk for both SafetyGlide and Eclipse, and currently touts "Virtually no splatter upon activation" as a "SAFETY" feature of the SafetyGlide.[7]

43. BD continues to create new advertisements touting Safety-Lok, SafetyGlide, and Eclipse as "safety-engineered devices" and "safety injection products."[8]

44. BD sales representatives undercut sales of Rectractable's VanishPoint® products by claiming that retraction harms the patient. Engaging retraction on the VanishPoint® before

[5] *See, e.g.*, http://www.bd.com/injection/products/pdf/BD_eclipse_brochure.pdf (on-line in July 2007, and, upon information and belief, for months before and since).

[6] *See id.*

[7] http://www.bd.com/injection/products/pdf/BD_safetyglide_needle_brochure.pdf ("SAFETY . . . Virtually no splatter upon activation").

[8] *See, e.g.*, http://www.bd.com/injection/products/pdf/BD_eclipse_brochure.pdf; *see also* http://www.bd.com/safety/products/injection/index.asp (on-line and copyrighted in 2007).

removing the needle from the patient not only does no harm but is also a critical safety feature because it eliminates the post-procedure window of exposure that occurs upon removing a needle from a patient.

45. Even though BD understands that eliminating the critical exposure period (after injection or blood-drawing and before disposal into a sharps container) increases safety, it nevertheless continues this false attack on VanishPoint® and retraction technology. For example, BD advertises its SafetyGlide and Eclipse with this and similar language: "Activation occurs after needle is withdrawn: no negative impact to the patient."[9]

46. Such advertising implies that devices, such as VanishPoint®, in which activation occurs before the needle is withdrawn do have a negative impact to the patient.

47. Despite the danger inherent in its non-retracting so-called "safety" syringes, BD has claimed interstate use of, and filed for U.S. registration of, the mark "Why can't it be zero?" Specimens of advertising that use this mark pair that question, "Why can't it be zero?" with this answer, "It can." Such advertising creates the false and misleading impression that use of BD's products will reduce needle sticks to "zero."

48. All of this false advertising damages both Retractable and the American public, in particular, healthcare workers. By promoting the Safety-Lok, SafetyGlide, and Eclipse as "safe" when in fact they are not, BD implies to healthcare workers and healthcare employers not only that the products provide protection from needlestick injuries, but also, and just as damaging, that purchase and use of such products will place the healthcare entity in "compliance" with the provisions of the Needlestick Prevention Act. Thus, false advertising allows BD to sell its high-profit-margin, unsafe "safety" products and needles to circumvent the

[9] *See, e.g.*, http://www.bd.com/injection/products/pdf/BD_safetyglide_needle_brochure.pdf *and* http://www.bd.com/injection/products/pdf/BD_eclipse_brochure.pdf.

intent of the Needlestick Prevention Act and thereby block adequate consideration of Retractable's clearly safer technology.

Antitrust Violations.

A. Relevant Markets and BD's Monopolies

49. BD's conduct alleged in this Amended Complaint affects interstate trade and commerce. BD's annual revenues are measured in billions of dollars, and BD's products are manufactured and sold throughout the United States, including in Texas. BD's conduct was intended to maintain and extend its market power in the nationwide markets for safety blood collection devices ("BCDs") and safety syringes and needles (collectively, "Safety Needle Devices").

50. BD was founded in 1897; its first product was an all-glass syringe. By the 1950s, BD had become the leading U.S. hypodermic syringe manufacturer. Its product line also included blood collection products and IV catheters.

51. In 1964, BD entered into a consent judgment with the United States Department of Justice that prohibited BD's continuation of monopolistic practices in the glass syringe market. That judgment, which is technically still in force, specifically related to only ***glass syringes*** even though BD was in the process of shifting its entire manufacturing and the same illegal marketing practices to ***plastic*** disposable syringes. Its "Plastipak" plastic disposable syringe was introduced in the 1960's and allowed BD to continue its monopolistic practices with impunity.

52. For decades now, BD has maintained dominance in the market for disposable syringes (conventional and safety), which replaced glass syringes. In 2005 BD was estimated to control over 70% of the United States market for syringes and needles. ("U.S. Syringes and Needle Markets", F876-54, 2-29, Frost & Sullivan, 2006.)

53. Additionally, BD has long enjoyed monopoly power in the conventional (non-safety) injection and drug infusion market. Even as the market for safety needle products has grown, conventional needle products still possess a significant share of the overall market. A recent study projected there will still be a 50-50 split of the market as late as 2012. ("U.S. Syringes and Needle Markets", F876-54, 1-5, Frost & Sullivan, 2006.) As a result, BD has a strong economic incentive to keep Retractable out of the market for safety needle products, not only so BD can maintain its prices for those products, but also so it can maintain its monopoly in non-safety product lines.

54. Almost all needle products sold today are marketed in both alleged "safety" and non-safety forms. Although safety and non-safety products perform the same function, safety products should reduce the risk of needlestick injury. The Needlestick Prevention Act has mandated use of "safer" products. BD and other manufacturers are able to charge, and healthcare workers are willing to pay, a higher price for Needle Products marketed as "safe," "safety," or "safety-engineered" products. As a consequence, safety and non-safety versions of these products are today in separate product sub-markets and have been since at least early 2004.

55. The relevant product markets impacted by BD's antitrust violations are the nationwide markets for manufacture and distribution of Safety Needle Devices. A monopolist in these markets would be able to maintain the prices of Safety Needle Devices above a competitive level without losing so many customers as to make the maintenance unprofitable. Each of these products constitutes a separate market with unique characteristics. BD's violations of the antitrust laws have foreclosed and continue to foreclose Retractable from the market for Safety Needle Devices.

56. Safety Needle Devices constitute a distinct market from conventional needle devices. The relevant market for the manufacture and distribution of Safety Needle Devices is a distinct market because both suppliers and purchasers view Safety Needle Devices as distinct products. Hospitals and healthcare workers distinguish between alleged safer needle devices and their counterpart devices because of user preference for a safer alternative and to avoid the costs involved in disease or death resulting from needlestick injuries. Federal and state laws and regulations mandating use of safer products also cause hospitals and healthcare workers to distinguish between conventional needle products and Safety Needle Devices. Thus, end users do not consider conventional needle products and Safety Needle Devices to be substitutes for each other.

57. Furthermore, manufacturers of conventional needle products cannot easily switch to manufacturing Safety Needle Devices because the two types of products require different patents and capital equipment, including both molds and assembly equipment unique to each device. Safety Needle Devices are significantly more complex products than conventional needle products, incorporating additional moving parts and distinctive design elements.

58. Safety syringes, and safety BCDs, each constitute a distinct relevant market because each product cannot properly be substituted for another for the same clinical use. A nurse cannot use a BCD to administer medication by injection, for example. End users do not consider these Safety Needle Devices to be substitutes for one another. In addition to these differences in product characteristics, the purchasers of these products differ: BCDs are often purchased for use in laboratories, while syringes are most often purchased by hospitals or clinics. Manufacturers cannot easily switch from producing one device, for example safety syringes, to another, such as safety BCDs, because the devices require different patents, production lines, and

regulatory approvals. Further, there are substantial barriers to entry facing any potential manufacturer of Safety Needle Devices. A potential entrant must have a patent on its own technology or license to use someone else's technology. There are also high capital costs in designing and manufacturing a medical device. High regulatory hurdles face all stages of manufacture and sale of medical devices.

59. In addition, Safety Needle Devices are also sold in at least two separate customer markets. The acute care market, composed of hospitals and related facilities that perform surgery on an in-patient basis, and alternate care facilities that provide long-term nursing care, out patient surgery, emergency care, physician services and the like, are recognized sub-markets of the overall healthcare market. Even though the same products may be marketed to both types of facilities, differences in volumes, distribution, pricing, and contracting mean that these are separate sub-markets. BD controls both of these sub-markets with its overall monopoly and/or market power, and has an especially tight grip on the acute care market.

60. According to an independent study published in 2006, reflecting data from 2005, BD has maintained monopoly power in the market for all needle products. BD had over 71 percent of the total syringe and needle market in 2005. BD had 88 percent of the BCD market in 2005. ("U.S. Syringes and Needle Markets", F876-54, 2-29, 3-14, Frost & Sullivan, 2006.) BD's market shares are greater within the acute care sub-market.

61. The relevant geographic market for the commerce at issue here is the United States. Both BD and Retractable sell their Safety Needle Devices throughout the United States. The Needlestick Prevention Act uniquely impacts the demand for Safety Needle Devices throughout the United States. Patent laws and the regulatory conditions for sales of Safety

Needle Devices also vary from country to country, making the United States a distinct geographic market.

B. BD's Unlawful Exclusionary Tactics

62. From and after July 2, 2004, BD has continued to employ various forms of exclusionary and otherwise anticompetitive contracts with healthcare facilities in order to frustrate, impair, and substantially foreclose competition from Retractable and all other actual or potential manufacturers of Safety Needle Devices. On information and belief, BD's contracts are often multi-year contracts that frequently require the other party to purchase exclusively from BD or to purchase a high percentage of its requirements from BD. Under BD's exclusionary contracts, the prices that healthcare facilities pay for BD's products are conditioned on the purchasers maintaining BD's market share by agreeing to fill all, or nearly all, their Safety Needle Device demand by purchasing BD products to the exclusion of competitive products.

63. Under these exclusionary and otherwise anticompetitive contracts, healthcare providers risk the forfeiture of substantial BD rebates, as a penalty, unless they purchase very high levels of their product needs from BD. Indeed, under BD's contracts, if a healthcare entity were to fall even slightly below BD's target level as the result of purchasing a competitor's needle products, the healthcare entity would be penalized by: (a) becoming obligated to pay higher prices for all or most BD products the entity purchases; (b) losing post-purchase rebates for all or most BD products it purchases; and/or (c) in some circumstances becoming obligated to repay ***past*** rebates that the healthcare entity received in connection with prior purchases of BD products**.** BD's contracts are unreasonable and have no business justification; the purpose and effect of these agreements is to maintain BD's monopoly.

64. BD's exclusionary penalty strategy works by penalizing healthcare entities for purchasing products from BD's competitors. BD's purchase requirements have the purpose and

effect of denying market access to Retractable and other potential and existing competitive manufacturers, thereby foreclosing and excluding them from the market.

65. BD also maintains its market power by unlawful bundling, or conditioning discounted prices or rebates for products on a healthcare entity's commitment to purchase BD products for most, if not all, of the entity's needs in each of various product categories. For example, through BD's bundling practices, a healthcare entity receives discounted prices or rebates for its purchases of several types of BD products, but only if the healthcare entity satisfies BD's requirements by buying a dominant amount of each of the different products in BD's bundle. The healthcare entity only earns rebates or discounts on a particular product if it satisfies the exclusivity, loyalty, market share, or other volume requirements for all the other products in the bundle. Upon information and belief, many of these BD contracts are multi-year contracts that require the return of past rebates or discounts if the healthcare entity does not meet all the present volume and exclusivity requirements.

66. Likewise, BD has bundled rebates and discounts on its conventional needles with rebates and discounts on its alleged "safety" needles. Thus, BD has been able to leverage its monopoly power in the market for conventional needle products to impede and substantially foreclose competition in the relevant market for Safety Needle Devices.

67. Similarly, BD bundles rebates for its needle products with unrelated healthcare products. Healthcare entities incur penalties even if they purchase BD products for all of their needs in numerous product categories, but buy even a small amount of a competitor's Safety Needle Products. The prospect of such a penalty creates disincentives that makes it economically impractical or impossible for a healthcare entity to purchase a BD competitor's

Safety Needle Products. BD's bundling practices exclude and foreclose competition in markets in which BD has market power and thereby unlawfully maintain BD's dominance.

68. Many of BD's competitors in the Safety Needle Device market are companies that concentrate in, manufacture, and sell specialized product lines. As a result, BD's penalty programs prevent Retractable and other BD competitors from competing on price for their specialized products because they are unable to offer equal, offsetting discounts or price reductions for those other products. Even if a BD competitor substantially reduces the price for its Safety Needle Devices, for example, that reduction will not compensate the healthcare entity for the loss of discounts or rebates BD would eliminate for other BD products in order to penalize the healthcare entity for shifting some or all of its Safety Needle Device purchases to the BD competitor. BD's practices reward healthcare purchasers for purchasing BD's Safety Needle Devices, in lieu of any other manufacturer's Safety Needle Devices, not because BD's Safety Needle Devices are better or cheaper (which they are not), but in order to retain greater discounts or concessions on products the other manufacturers do not produce.

69. A simple illustration with hypothetical rebate amounts demonstrates how BD uses multi-product rebates to exclude competition from competitors such as Retractable, which are essentially single product manufacturers. BD can profitably offer a $5 rebate on each of nine products in a bundle (safety syringes, alcohol swabs, lancets, insulin syringes, insulin pens, pen needles, thermometers, braces, and glucose tablets), provided that the healthcare entity meets the market share or exclusivity requirements for each of the nine products. Assuming the healthcare entity does so, it will get a $45 rebate. Because Retractable does not manufacture the same broad range of products as BD, it would have to offer a $45 rebate on its safety syringes to compete for the healthcare entity's business and make up for the rebates the healthcare entity

would forfeit if it purchased the Retractable safety syringes along with the other eight BD products. To the extent BD's contract requires the return of earlier rebate payments if the healthcare entity does not satisfy current exclusivity terms, Retractable would have to offer an even larger rebate to compensate. While Retractable could match BD's $5 rebate on safety syringes and still make a profit, it could not afford to offer a $45 rebate. This illustration shows how BD is able to maintain net prices (invoice price minus the rebate) that are above Retractable's prices and still maintain monopoly power.

70. To make up for all of the bundled rebates the healthcare entity would give up if it purchased the Retractable safety syringes, under this illustration Retractable would have to give its safety syringes away, or in some cases, pay the healthcare entity to take them (because the combined rebates on all of the products in BD's bundle is likely to be greater than the entire price of the safety syringes made by Retractable). No producer of Safety Needle Devices that was as equally efficient as BD and that produced products of equal quality would be able to compete with BD's bundled rebates unless it had as broad an array of products as BD.

71. Likewise, upon information and belief, BD's bundle rebates, as described above, are exclusionary because after the full amount of BD's rebates given on all bundled products are allocated to the Safety Needle Devices, BD's resulting price is below its incremental production cost for its Safety Needle Devices.

72. BD's anticompetitive contracts are held in strict confidence by BD and BD requires its healthcare customers to keep the contracts confidential. Upon information and belief, if a healthcare customer were to disclose the terms of its BD contract to Retractable, the customer would risk a lawsuit for breach of contract or misuse of trade secrets. Furthermore, the healthcare entity would be threatened with the loss of rebates on all the bundles products. As a

result, Retractable has not seen any of the specific terms of the contracts. Retractable believes that BD's contracts contain additional anticompetitive terms that restrain competition other than those alleged in this Amended Complaint.

73. After July 2, 2004, Retractable expanded its sales force and stepped up its efforts to market VanishPoint® syringes. To spur sales and increase market share, Retractable reduced the price of VanishPoint® syringes below those of other "safety" products then on the market. Even with low prices at nearly the same levels as those for conventional non-safety syringes, the hospitals did not respond by purchasing VanishPoint® syringes in greater volumes. Retractable's price reduction program, intended to provide hospitals with a strong economic incentive to purchase VanishPoint® syringes, was blocked by BD's exclusionary contracts, BD's bundling practices, and other monopoly-protecting arrangements BD had with hospitals that would have penalized the hospitals for purchasing VanishPoint® syringes.

74. In addition, 98 percent of American hospitals are members of Group Purchasing Organizations ("GPOs"). GPOs offer most products used by their member hospitals. Hospitals join GPOs through membership contracts that require member hospitals to do most or all of their purchasing through the GPO. GPOs, in turn, enter into multi-year contracts with manufacturers and suppliers of products used by hospitals. The resulting list of GPO suppliers constitutes the "approved" list for purchases by member hospitals. Upon information and belief, BD has entered into contracts with GPOs that require the GPOs' member hospitals to purchase high levels of their Safety Needle Devices requirements from BD in order to maintain favorable price discounts. In addition, on information and belief, BD enters into so-called "second event" or "aggregation" contracts directly with hospitals and hospital groups. These are exclusive dealing

arrangements that provide for additional "discounts" to hospitals, and unless the hospitals agree to these arrangements, they are penalized by having to pay higher prices for BD products.

75. Thus, although Retractable has contracts with several large GPOs and is therefore on the approved list of vendors for the GPOs' hospital members, in reality, purchases of Safety Needle Devices from Retractable would subject hospitals to financial penalties in the forms of reduced "discounts" or rebates from BD, despite the fact that the VanishPoint® syringe is the superior product and is priced competitively. BD also contracts directly with hospitals and monitors its sales of a range of products to those hospitals, penalizing the hospitals if they purchase goods, including Retractable's Safety Needle Devices, that are not part of the contract.

76. The result of BD's anticompetitive practices is that competition in the Safety Needle Devices markets is artificially suppressed, the cost of products in these markets is inflated, the quality of the products is reduced because the monopolist BD is under no competitive pressure to innovate its products or reduce costs, and healthcare workers are denied the opportunity to use much safer Safety Needle Devices. BD's anticompetitive acts have substantially decreased competition in the markets for Safety Needle Devices throughout the United States.

C. BD Degrades Drug Delivery Safety to Protect its Market Dominance

77. BD has sacrificed patient safety by designing, marketing, and promoting so-called "needleless" infusion syringe systems designed to screw onto specially-made BD ports in drug delivery lines attached to hospital patients. Either alone or in combination with other large medical device manufacturers, BD redesigned disposable drug delivery systems used in hospitals to deliver fluids and drugs to patients in a manner that forecloses use of VanishPoint® syringes. The new infusion system requires a new BD port (costing substantially more than the old ports)

and an intermediate connector piece that allows only a BD-manufactured syringe to be screwed into the port for drug delivery.

78. BD's new infusion system guarantees use of BD's "needleless" syringes for a large percentage of hospital usage and insures that VanishPoint® syringes cannot be used to deliver drugs in the hospital environment. But in order to deliver medications, BD's alleged "safety" infusion syringe system requires procedures that increase the potential for contamination of a fluid line linked directly to the patient's blood system. At least one hospital has reported that such "open" systems increased infectious disease risk.

79. On information and belief, BD knew or should have known that its "open" infusion systems, while effective in maintaining BD's dominant market share, would needlessly increase infection risks to patients. Those increased risks could have been avoided through the use of a syringe designed with a fully retracting needle to be used with a sealed, pierceable port. But BD did not have a retractable syringe technology. To foreclose Retractable from this significant segment of the hospital market, BD designed its new infusion system to use only BD syringes and thereby placed patients at an increased risk of hospital-borne infections.

D. BD Suppresses Healthcare Worker Knowledge of Retractable's Products

80. Once nurses and hospital medical staff become aware of Retractable's safety syringes, they often demand access to these products. One analyst noted as recently as 2005: "…[E]nd users and distributors are mostly unaware of the retractable-syringe technology." ("Disposable Syringe Markets" p. 11, TriMark Publications, Sept. 2005.)

81. BD has caused or induced potential customers and trade shows to bar and exclude Retractable's sales staff from entering premises or demonstrating the advantages of the VanishPoint® syringes. For example, Retractable has been barred from one or more trade shows, even though the purpose of the shows was to demonstrate available safety technology to medical

staff. Hospital and trade show personnel have tried to justify the exclusion of Retractable's sales personnel by saying their facility is under contract with BD, exclusive to BD, or standardized with BD.

E. BD Controls Market Access By Making Indirect Payments to Hospital Decision Makers

82. Other anticompetitive acts include various schemes for making indirect payments to hospital purchasing executives, chief executive officers, and others within the healthcare industry in exchange for exclusive access. One such scheme, documented by the Connecticut Attorney General, involved membership in an anticompetitive, exclusive "club" of healthcare industry vendors and hospital chief executives: the Healthcare Research and Development Institute ("HRDI").

83. BD and other vendors paid $40,000 for membership privileges in HRDI, enabling them direct access to CEO's from the nation's premier hospitals and healthcare institutions. The CEO members were paid an average of $20,000 to $25,000 annually to attend conferences with luxury accommodations for them and their spouses and to meet with vendors. Some of the CEO's were paid upwards of $40,000 to $50,000. HRDI's "Rule of 2" boosted leverage for the participating vendors by allowing only two vendors in a particular line of commerce access to these CEO's.

84. In announcing a settlement in January 2007, the Connecticut Attorney General stated as follows:[10]

> HRDI claimed to offer health care consulting services to industry players. In reality, it was an exclusive network that shut out potential competitors in various health care markets — everything from pharmaceuticals, syringes, medical devices and financial and consulting services.

[10] *See* http://www.ct.gov/ag/cwp/view.asp?Q=331254&A=2788

> These practices threatened to inflate health care costs to patients and taxpayers — stifling competition in almost every health care supply and services market. . . .
>
> . . . vendors intentionally exploited the opportunities provided by HRDI, resulting in an uneven playing field and less competitive selling environment. Vendors gained direct access to hospital CEOs who potentially wielded influence over service and supply purchasing decisions at their respective hospitals.

85. BD was a paying member of HRDI since July 2004 through at least January 2007 and illegally used its membership to exclude Retractable from Safety Needle Device markets.

86. Upon information and belief, BD continues the same or similar practices under the guise of membership in other organizations, including a HRDI spin-off, the National Center for Healthcare Leadership.

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 5,632,733

87. All preceding paragraphs of this Amended Complaint are incorporated herein by reference as if fully set forth at length.

88. Plaintiff Retractable is the exclusive licensee for, and has the right to sue in its own name on, United States Patent No. 5,632,733 ("the '733 patent"), issued May 27, 1997, a copy of which is attached as Exhibit A. Plaintiff Shaw is the inventor of and owns all right, title, and interest in the '733 patent, subject to the exclusive rights of Retractable. The maintenance fees for the '733 patent have been timely paid, and the '733 patent has not been invalidated or found to be unenforceable in any prior litigation.

89. At all times relevant to this action, Retractable and Shaw have complied with the notice provisions of 35 U.S.C. § 287 as it concerns the '733 Patent.

90. BD has directly, indirectly, and/or contributorily infringed the '733 Patent by manufacturing, using, selling, offering for sale and/or importing into the United States retractable

syringes covered by the '733 Patent, and has induced and/or contributed to the infringement of the '733 Patent by others in the United States and within this District, and will continue to do so unless enjoined by this Court.

91. No right or license to practice the invention claimed in the '733 patent has been granted to BD.

92. Retractable and Shaw have been damaged by BD's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 6,090,077

93. All preceding paragraphs of this Amended Complaint are incorporated herein by reference as if fully set forth at length.

94. Plaintiff Retractable is the exclusive licensee for, and has the right to sue in its own name on, United States Patent No. 6,090,077 ("the '077 patent"), issued July 18, 2000, a copy of which is attached as Exhibit B. Plaintiff Shaw is the inventor of and owns all right, title, and interest in the '077 patent, subject to the exclusive rights of Retractable. The maintenance fees for the '077 patent have been timely paid, and the '077 patent has not been invalidated or found to be unenforceable in any prior litigation.

95. At all times relevant to this action, Retractable and Shaw have complied with the notice provisions of 35 U.S.C. § 287 as it concerns the '077 Patent.

96. BD has directly, indirectly, and/or contributorily infringed the '077 Patent by manufacturing, using, selling, offering for sale and/or importing into the United States retractable syringes covered by the '077 Patent, and has induced and/or contributed to the infringement of the '077 Patent by others in the United States and within this District, and will continue to do so unless enjoined by this Court.

97. No right or license to practice the invention claimed in the '077 patent has been granted to BD.

98. Retractable and Shaw have been damaged by BD's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 5,578,011

99. All preceding paragraphs of this Amended Complaint are incorporated herein by reference as if fully set forth at length.

100. Retractable is the exclusive licensee for, and has the right to sue in its own name on, United States Patent No. 5,578,011 ("the '011 patent") issued November 26, 1995, a copy of which is attached as Exhibit C. Plaintiff Shaw is the inventor of and owns all right, title, and interest in the '011 patent, subject to the exclusive rights of Retractable. The maintenance fees for the '011 patent have been timely paid, and the '011 patent has not been invalidated or found to be unenforceable in any prior litigation.

101. At all times relevant to this action, Retractable and Shaw have complied with the notice provisions of 35 U.S.C. § 287 as it concerns the '011 Patent.

102. BD has directly, indirectly, and/or contributorily infringed the '011 Patent by manufacturing, using, selling, offering for sale and/or importing into the United States retractable syringes covered by the '011 Patent, and has induced and/or contributed to the infringement of the '011 Patent by others in the United States and within this District, and will continue to do so unless enjoined by this Court.

103. No right or license to practice the invention claimed in the '011 patent has been granted to BD.

104. Retractable and Shaw have been damaged by BD's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

WILLFUL INFRINGEMENT

105. BD's acts of infringement have been willful and in deliberate disregard of the '733, '077 and '011 Patents, and this is an exceptional case under 35 U.S.C. § 285.

106. BD has known that its non-infringing, so-called "safety" syringes, which use add-on safety features, are not safe to use in practice and that Plaintiffs' patented retractable needle technology had to be utilized in order to achieve a cost effective, manufacturable, safe syringe. BD's failures in an attempt to use alternate technology are evidence of the worth of Plaintiffs' technology and BD's willful intent, namely, to copy and use Plaintiffs' technology for itself.

107. BD's infringing Integra syringe products are promoted as being superior to VanishPoint® syringes, when, in fact, they are infringing variants of the basic patented features of Plaintiffs' technology that deliver safety and reliability to the healthcare worker.

108. BD had full knowledge of, and has attempted to obtain rights under, the patents-in-suit and decided to copy Plaintiffs' technology and use it to ward off growing demands for safer products in the marketplace.

COUNT 4: FALSE ADVERTISING IN VIOLATION OF SECTION 43(A) OF THE LANHAM ACT

109. All preceding paragraphs of this Amended Complaint are incorporated herein by reference as if fully set forth at length.

110. BD has, in connection with its Safety-Lok, SafetyGlide, and Eclipse syringes and blood collection devices, used in interstate commerce words, terms, names, and combinations thereof, and false and misleading descriptions and representations of fact, in commercial

advertising and promotion to misrepresent the nature, characteristics, and qualities of the Safety-Lok, SafetyGlide, and Eclipse syringes, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

111. BD has misleadingly and/or falsely used the words, terms, and names "safe," "safety," or "safety-engineered" and various other similar descriptions and phrases (e.g., "Why can't it be zero? It can.") in commercial advertising and promotion to describe the nature, characteristics, and qualities of its syringes or blood-collection needles, such as Safety-Lok, SafetyGlide, and Eclipse, all in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

112. The foregoing descriptions, representations, and statements are illustrative, not exhaustive, and were made in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

113. Each of BD's false descriptions, representations, statements, advertising, and promotions, described herein or otherwise, has been intentional and willful, and has deceived or has had the tendency to deceive a substantial portion of the intended audience in a material manner, which has influenced or has had the likelihood to influence purchasing decisions.

114. Moreover, BD's wrongful acts have caused, and will continue to cause, Retractable to incur substantial damages, including, but not limited to, declining sales, loss of goodwill, lost profits, and loss of market share. Retractable therefore seeks recovery from BD of all amounts it is entitled to under 15 U.S.C. § 1117(a), including, without limitation: (1) BD's profits related to its false and misleading descriptions, representations, statements, advertisements, and promotions; (2) all damages sustained by Retractable; (3) the costs of this

action; (4) treble damages, (5) reasonable attorneys' fees; and (6) an additional amount that the Court considers just.

115. Retractable pleads for prospective injunctive relief to enjoin BD's ongoing false and misleading descriptions, representations, statements, advertisements, and promotions under 15 U.S.C. § 1116(a).

116. BD has acted with unclean hands, and Retractable's claims under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), further the public interest.

COUNT 5: VIOLATIONS OF THE SHERMAN AND CLAYTON ACTS

117. All preceding paragraphs of this Amended Complaint are incorporated herein by reference as if fully set forth at length.

118. The relevant geographic market is the United States. As pleaded above, the relevant market segments for Safety Needle Devices are acute care and alternate care medical facilities. The relevant product markets for Safety Needle Devices are safety syringes and needles and safety BCDs. BD has monopoly and/or market power in these relevant markets.

119. BD has ***not*** maintained it monopoly and/or market power in the relevant markets as a result of superior product, business acumen, or historical accident. BD has specifically intended, and continues to intend, through its alleged conduct, to willfully maintain its monopoly and/or market power, control prices, exclude competitors, harm consumers, and destroy competition in the relevant markets. Through the activities alleged above, among others, BD has gained, maintained, extended, and attempted to gain monopoly power in the acute care and alternate care markets for Safety Needle Devices in violation of Section 2 of the Sherman Act.

120. BD has no legitimate business justification for its exclusionary, anticompetitive conduct.

121. As a direct and proximate result of BD's unlawful actions, Retractable has suffered injury to its business and property. If BD's illegal conduct is not enjoined, Retractable will suffer irreparable harm, and the markets for Safety Needle Devices will remain distorted and substantially foreclosed to the detriment of consumers in the market. Advances in Safety Needle Devices technology that could prevent needlestick injuries and thereby prevent disease and save lives will continue to be excluded from the market because BD exercises monopoly and/or market power to exclude competitors and set prices.

122. Further, BD has made sales of Safety Needle Devices and has set prices charged and discounts and rebates granted on those sales based on the condition, agreement, or understanding that BD's buyer will not purchase Retractable's products.

123. BD's exclusive dealing violates Section 3 of the Clayton Act because it has foreclosed Retractable from substantial portions of the markets for Safety Needle Devices and because it substantially lessens competition in those markets and tends to maintain BD's monopoly and/or market power over those markets.

124. BD's bundling practices also violate Section 2 of the Sherman Act and Section 3 of the Clayton Act because they exclude Retractable and other BD competitors from substantial portions of the markets for Safety Needle Devices and because such practices substantially lessen competition in those markets and tend to maintain BD's monopoly over those markets.

125. BD's willful taking of Retractable's technology, resulting in the tort of patent infringement, constitutes an illegal act that substantially lessens competition and tends to maintain BD's dominance over the market for Safety Needle Devices.

126. BD's false advertising of its syringe and BCD products as "safe," "safety," "safety-engineered," and various other similar descriptions in commercial advertising and

promotion to describe the nature, characteristics, and qualities of the Safety-Lok, SafetyGlide, and Eclipse syringes constitute illegal acts that substantially lessen competition and tend to maintain BD's dominance over the markets for Safety Needle Devices.

127. BD's various schemes for making indirect payments to hospital purchasing executives, chief executive officers, and others within the healthcare industry have excluded Retractable and other BD competitors from the Safety Needle Devices markets. These anticompetitive practices, which allow BD to have direct access to hospital executives who wield influence over purchasing decisions, have inflated healthcare costs to patients, stifled competition, and created an uneven playing field for BD's competitors.

128. From and after July 2, 2004, Retractable has been directly and proximately damaged by losses of sales and profits resulting from BD's exclusive dealing, bundling arrangements, patent infringement, false advertising, indirect payments to decision makers at hospitals, and other monopolistic practices. Retractable seeks damages, treble damages, reasonable attorneys' fees, costs of court, and all other relief available to it under the antitrust laws. Retractable will be irreparably harmed if BD's exclusive dealing and bundling arrangements, patent infringement, and false advertising are not enjoined.

129. Alternatively, BD has specifically intended, and continues to intend, through its alleged conduct, to control prices, exclude competitors, and destroy competition in the relevant markets for Safety Needle Devices. Through the activities alleged in the paragraphs above, among others, BD has attempted to gain monopoly power in the markets for Safety Needle Devices. BD's predatory and anticompetitive conduct presents a dangerous probability that BD will succeed in monopolizing the Safety Needle Devices markets because BD already has market power in those markets, which contain high barriers to entry in the form of capital costs,

intellectual property requirements and costs, and other burdens. As a direct and proximate result of BD's anticompetitive conduct alleged herein, Retractable has been injured in its business and property and suffered substantial lost profits, and will suffer irreparable harm if BD is not enjoined from continuing its illegal course of conduct.

COUNT 6: TEXAS ANTITRUST ACT

130. All preceding paragraphs of the Amended Complaint are incorporated herein by reference as if fully set forth at length.

131. BD's conduct outlined in the federal antitrust violations detailed above also violates the Texas Free Enterprise and Antitrust Act of 1983, Tex. Bus. & Com. Code Ann. § 15.01 *et seq.* (Vernon 2003). Retractable seeks an injunction, an award of damages, treble damages, recovery of its reasonable attorneys' fees, and all other relief available under said Texas Act. If BD's illegal conduct is not enjoined, Retractable will be irreparably damaged and Texas markets for Safety Needle Devices will be substantially foreclosed to competition.

COUNT 7: UNFAIR COMPETITION

132. All preceding paragraphs of this Amended Complaint are incorporated herein by reference as if fully set forth at length.

133. BD's alleged tortious conduct constitutes unfair competition in violation of the common law. BD and Retractable are competitors. BD has unfairly competed with and sought to destroy Retractable's business.

134. BD's conduct has damaged Retractable.

INJUNCTIVE RELIEF

135. All preceding paragraphs of this Amended Complaint are incorporated herein by reference as if fully set forth at length.

136. Retractable and Shaw are entitled to a permanent injunction preventing BD from continuing to infringe the '077, '733, and '011 Patents.

137. Retractable is entitled to a permanent injunction preventing BD from continuing to advertise its Safety-Lok, SafetyGlide, and Eclipse syringes using false and misleading descriptions and representations of fact, such as "safe," "safety," and "safety-engineered."

138. Retractable is entitled to a permanent injunction enjoining BD from continuing actively to exclude Retractable from the markets described herein, and requiring BD to take corrective action to remedy distortions in said markets caused by BD's continuing violations of the federal and Texas antitrust laws. Injunctive relief would greatly serve the public interest because the public has an interest in competitive markets and because Retractable's products could prevent more needlestick injuries, which would thereby prevent more instances of disease and death.

139. BD's violations of federal and Texas law are continuing, and BD has demonstrated that it will continue in all of the conduct described herein unless enjoined. Retractable is threatened with irreparable harm from these continuing and future violations.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff Retractable Technologies, Inc. and Plaintiff Thomas J. Shaw pray that Defendant Becton Dickinson and Company will be cited to appear and answer herein and for Judgment of this Honorable Court as follows:

(a) BD be adjudged and decreed to have directly, indirectly, and/or contributorily infringed the '733 Patent, the '011 Patent, and the '077 Patent;

(b) BD be adjudged and decreed to have willfully and deliberately infringed the '733 Patent, the '011 Patent, and the '077 Patent;

(c) BD be ordered to pay actual damages to Retractable and Shaw, but not less than a reasonable royalty, by reason of BD's infringement of the '733 Patent, the '011 Patent, and the '077 Patent together with prejudgment interest, costs and increased damages pursuant to 35 U.S.C. § 284;

(d) A permanent injunction be entered against BD, and its officers, agents, servants and employees, and all entities and individuals acting in concert with them, to permanently restrain any further infringement of the '733 Patent, the '011 Patent, and the '077 Patent;

(e) This case be declared an "exceptional case" within the meaning of 35 U.S.C. §285 and reasonable attorneys' fees, costs and treble damages be awarded to Plaintiffs;

(f) Enjoining BD from continuing the anticompetitive conduct alleged in this Amended Complaint;

(g) Ordering BD to take corrective steps to end the foreclosure of the relevant market and create a competitive market for Safety Needle Devices and to remedy the market distortions created by its past and continuing violations of the United States antitrust laws;

(h) Awarding Retractable treble damages resulting from BD's antitrust violations;

(i) Awarding Retractable (i) BD's profits, (ii) Retractable's damages, and (iii) costs of the action, pursuant to 15 U.S.C. § 1117(a);

(j) Awarding Retractable all reasonable attorneys' fees allowed by statute, expert fees, costs, pre-judgment interest, and post-judgment interest; and

(k) Granting all such other relief, at law and in equity, to which Plaintiffs are entitled.

JURY DEMAND

Plaintiffs demand a trial by jury as is their right under the Seventh Amendment to the Constitution of the United States or as given by statute. FED. R. CIV. P. 38.

Dated: September 28, 2007

Respectfully submitted,

/s/ Roy W. Hardin (by permission Otis Carroll)__

Roy W. Hardin
Texas Bar No. 08968300
George E. Bowles
Texas Bar No. 02743300
Michael V. Powell
Texas Bar No. 16204400
Bradley C. Weber
Texas Bar No. 21042470
Paul Schuster
Texas Bar No.00784931
Stephen D. Wilson
Texas Bar No. 24003187
LOCKE LIDDELL & SAPP PLLC
2200 Ross Avenue, Suite 2200
Dallas, Texas 75201-6776
Telephone: (214) 740-8000
Facsimile: (214) 740-8800
E-mail: rhardin@lockeliddell.com

OF COUNSEL:

Otis Carroll
State Bar No. 03895700
Deborah Race
State Bar No. 16448700
IRELAND, CARROLL & KELLEY, PC
6101 S. Broadway, Suite 500
Tyler, Texas 75703
Tel. (903) 561-1600
Fax (903) 581-1071
Email: Fedserv@icklaw.com

ATTORNEYS FOR PLAINTIFFS,
RETRACTABLE TECHNOLOGIES, INC. and
THOMAS J. SHAW

CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3). Any other counsel of record will be served by facsimile transmission and/or first class mail this 28th day of September, 2007.

/s/ Otis Carroll

EXHIBIT A

US005578011A

United States Patent [19]

Shaw

[11] Patent Number: 5,578,011

[45] Date of Patent: Nov. 26, 1996

[54] **TAMPERPROOF RETRACTABLE SYRINGE**

[76] Inventor: **Thomas J. Shaw**, 1510 Hillcrest, Little Elm, Tex. 75068

[21] Appl. No.: **438,954**

[22] Filed: **May 11, 1995**

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/110**; 604/195

[58] **Field of Search** 604/110, 187, 604/192, 195, 198, 263, 220, 218

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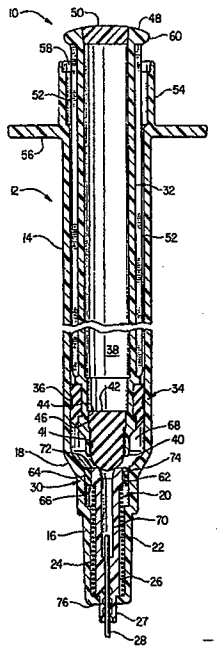
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Harris, Tucker & Hardin, P.C.

[57] **ABSTRACT**

A tamperproof retractable non-reusable syringe has a one piece hollow outer body with a barrel for a slidable plunger, a transition zone and a smaller diameter nose portion. An elongated needle holder and spring combination is installable from the rear of the outer body, guided into the nose portion and held by cooperating inwardly and outwardly facing surfaces oriented in the direction of retraction at the most constricted past of the transition zone where the nose begins. The plunger has an opening with a dislodgable stopper for receiving parts of the retraction mechanism. The stopper and the head of the needle holder are of significantly reduced diameter from the injection fluid chamber to resist blowing out prematurely. In one embodiment the head of the needle holder is surrounded by a separable retainer member which is slidingly removed by contact with the tip of the plunger after the stopper is mostly or fully removed to avoid cumulation of force required for retraction after the injection. In a second embodiment the head of the needle holder is clamped and held by constricting forces imposed by stress on the outer body induced by interference fit. Release occurs by slight expansion on the barrel by contact of the plunger tip with a small internal ramp in the outer barrel. Both embodiments have a plunger cap configured to enter an opening in the outer body to provide an additional tamperproof feature.

34 Claims, 4 Drawing Sheets



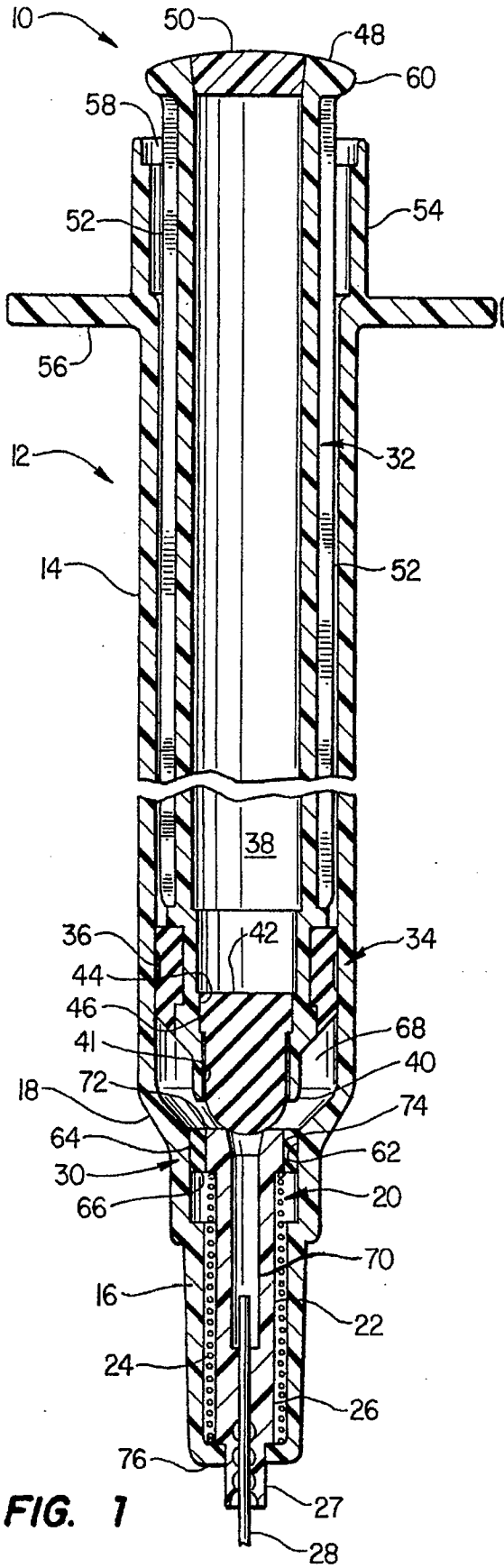

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FIG. 1

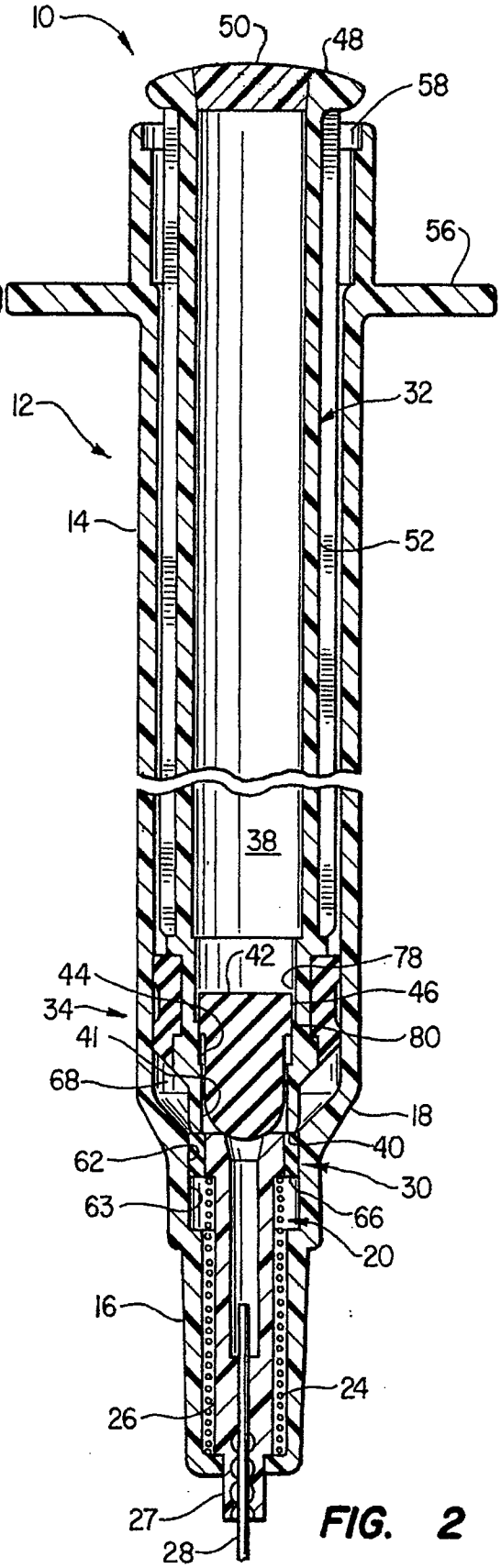
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FIG. 2

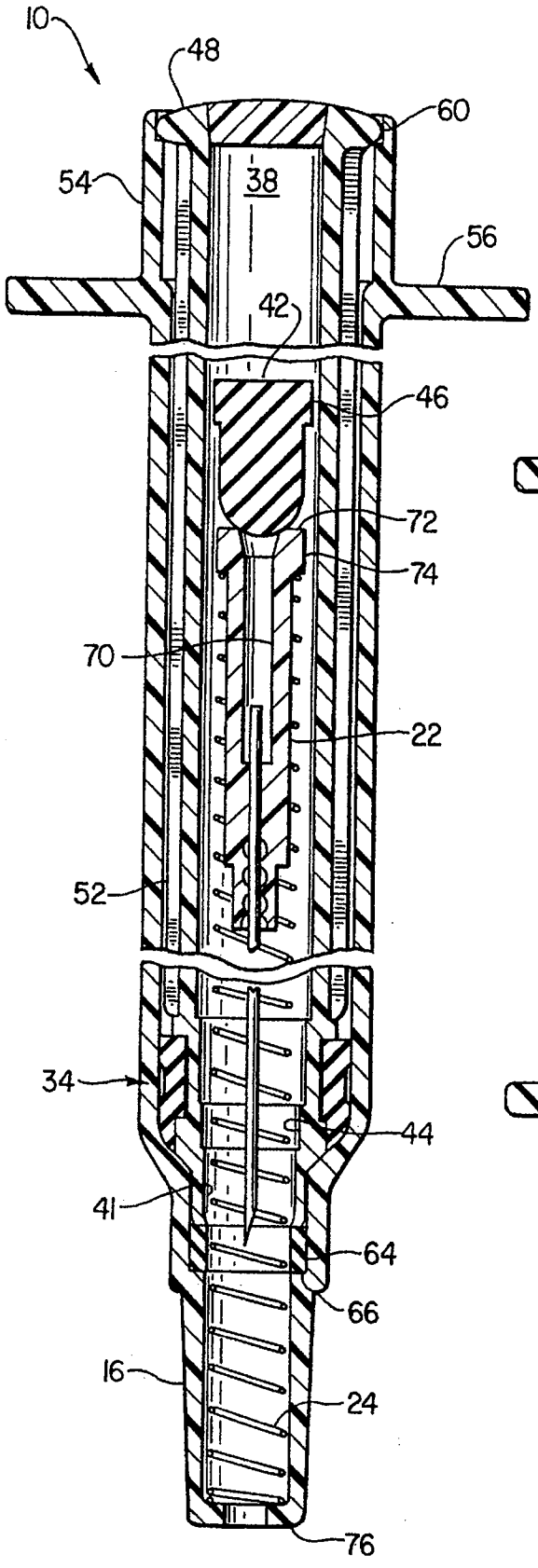

FIG. 3

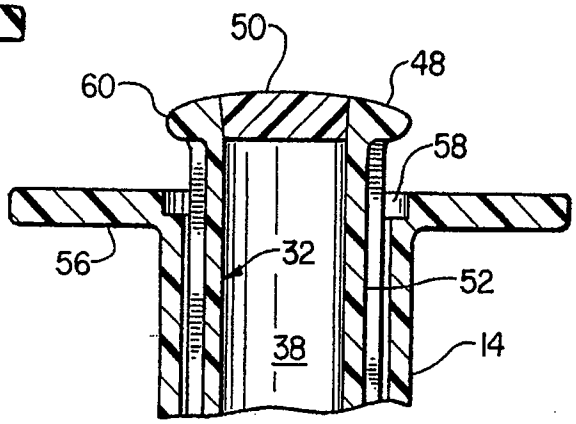

FIG. 4A

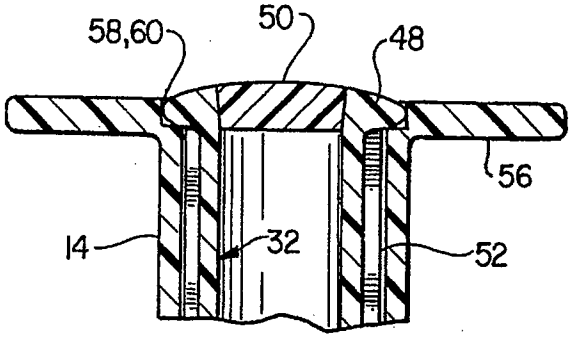

FIG. 4B

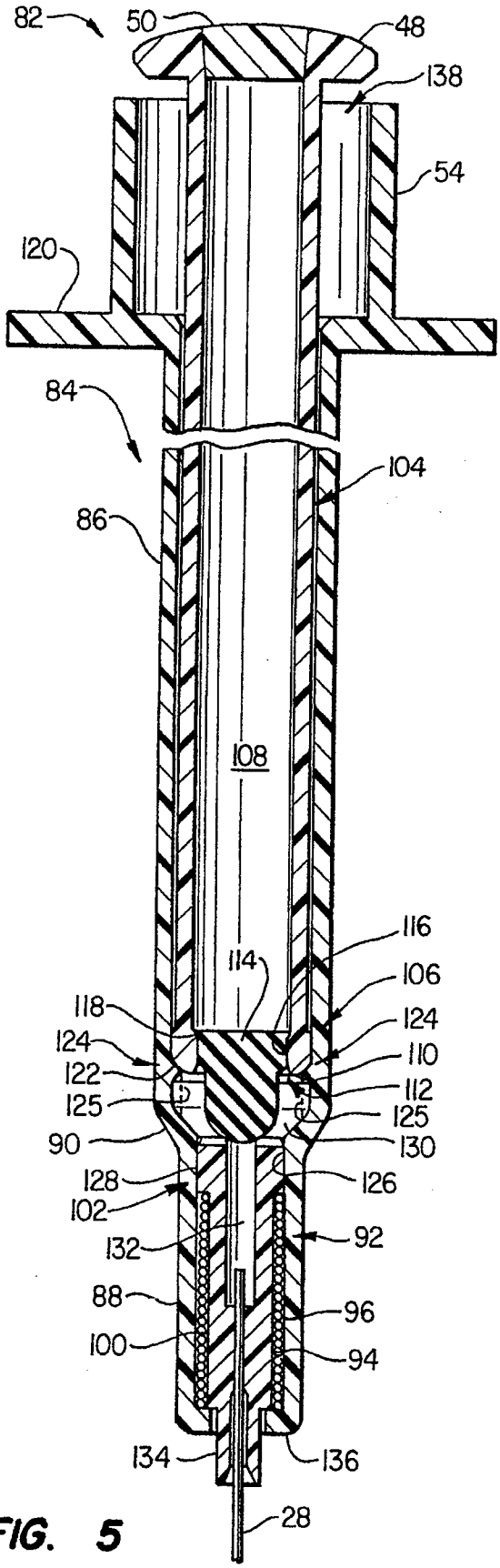
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FIG. 5

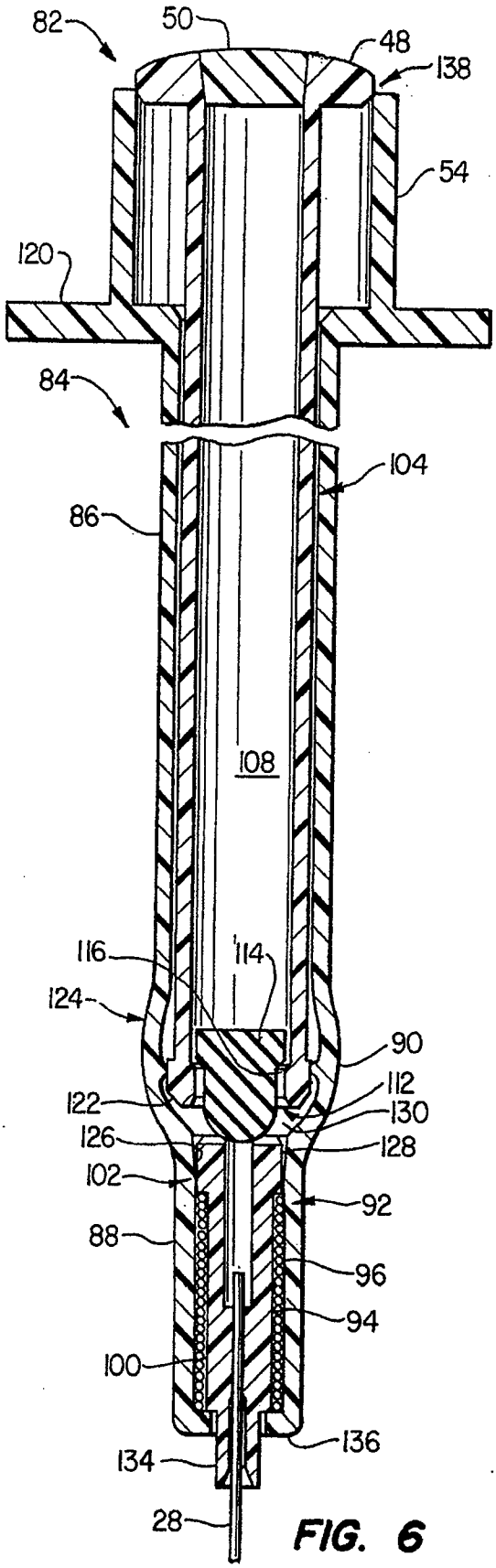
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FIG. 6

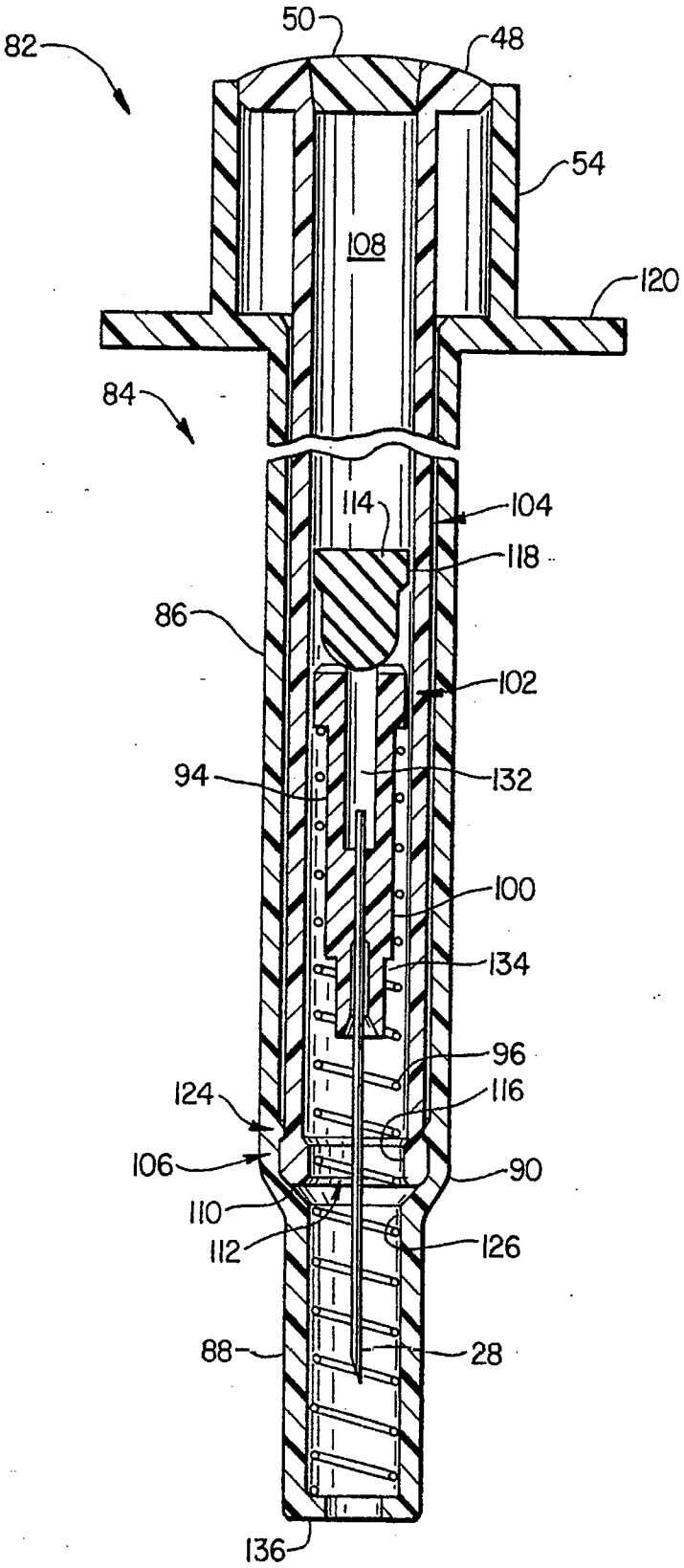
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FIG. 7

TAMPERPROOF RETRACTABLE SYRINGE

FIELD OF THE INVENTION

This invention relates to a medical device, and more particularly to a retractable syringe suitable for mass production and assembly having a low triggering force and high blowout pressure which is nonreusable after one use.

BACKGROUND OF THE ART

A major cause to the spread of AIDS in the general population is the presence of IV drug users who share and reuse hypodermic syringes to inject drugs. Infection can be spread from AIDS patients in hospitals and medical facilities through accidental needle sticks from needles used on infected patients. Used syringes with extended needles present a risk to medical personnel and sanitation employees and others in the disposal chain.

The gravity of the threat posed by AIDS and the fact that the main vector of the spread of the dreaded disease is through reuse of syringes by IV drug users has resulted in intense activity to develop the most practical, most reliable, easily assemblable, mass-producible syringe.

There are a number of syringes of different designs which have needles which will retract at the end of the injection cycle. Most of these have never reached the market because of various deficiencies. Prime among the usual deficiencies of the prior art are problems of complexity, reliability, cost and ease of use. The most commonly used syringes are 1 cc and 3 cc syringes which must be mass-produced at the rate of millions per day. Cost is a significant factor both in manufacture of the parts and assembly of the device. High speed production requires molds with 64 cavities or more to reduce unit cycle time. Therefore, molded structures within the barrel that require collapsing core pins such as are shown in much of the art are unlikely to be producible at competitive costs.

One of the problems of the prior art of retractable syringes is the shear number and complexity of parts which must be formed and assembled. Other problems with the prior art are dependence on flexing or breaking of internal parts by the plunger in order to release the retraction mechanism and use of a diaphragm at the end of the plunger which must be penetrated by a needle holding member and spring. These structures present serious quality control and assembly problems. Small broken off pieces can present a risk of hang-ups. Hooks are often used to releaseably secure retraction mechanisms. Hooks present difficult holding and control problems, may cause retention of air bubbles upon filling and may be undesirably temperature sensitive.

The prior art frequently has a two-piece barrel in order to be able to assemble a retraction device in the nose. This requires at least an additional part and assembly step. It is still necessary to pass the sharp injection needle through a small opening often compressing a spring before the two parts can be assembled. The tiny needles are produced in the form of coil tubing and vary significantly from straightness after they are cut to length. This leads to difficult assembly problems if the needle must be passed through a small opening. The extremely sharp tip will catch the edge of a hole and jam the production line.

The rare prior art that employs a front mounted retraction mechanism in a one-piece barrel with a plugged hollow plunger, Tsao U.S. Pat. No. 5,084,018, among other things does not show reduced barrel area to prevent excessive blowout pressure, employs engaging flanges to secure all retraction parts, requires concurrent distortion of internal parts and flanges to effect release cumulating force required to retract and requires ventilation holes because of a compartmented barrel.

The prior art has not produced a retractable nonreusable tamperproof syringe for mass production and assembly which is simple, reliable, cost effective, easy to use and retract, looks like a conventional syringe, has few parts which are easy to make and assemble, is not temperature sensitive and not subject to danger of premature retraction.

The prior art has not recognized a retraction mechanism with separable parts that relies entirely on clamping force or friction at a smooth walled reduced diameter transition zone in the barrel with mating lands which are slidably or separably released in response to relatively low thumb pressure while having resistance to premature retraction and high blowout pressure resulting from high pressure produced in the fluid chamber during an injection. The prior art has not recognized that such a structure can be molded as a one piece outer body over a core that can be pulled out from behind allowing the retraction mechanism to be easily pushed into place from behind, steered by the narrow nose portion. Neither does the prior art in such a combination realize the desirable non-cumulation of forces resisting retraction in order to minimize the thumb force required, having a most simple tamperproof feature and the fewest number of easily made parts. These features and more are found in the inventive combination herein further disclosed which is especially suited for high speed production and assembly at low cost.

SUMMARY OF THE INVENTION

The invention is a reliable retractable tamperproof syringe having multiple tamperproof features which operates on a principle which permits low cost parts which are few in number and well suited for high speed mass production and assembly. The syringe structure features a one piece hollow outer body having a longitudinally extending wall which is stepped. The wall comprises an elongated barrel and nose with a transition zone connecting the barrel and nose. The nose has a reduced diameter relative to the barrel. The outer body has an inwardly facing surface in the wall at the most constricted part of the transition zone where the nose begins. A plunger assembly is disposed partially within the elongated barrel with an end cap for depression of the plunger extending from an opening in the back of the barrel. The head of the plunger, which has a retraction cavity for receiving parts of a retraction mechanism, moves in slidable sealed contact with the interior of the barrel.

A retraction mechanism is lodged in the nose of the body. The retraction mechanism comprises an elongated needle holder and spring combination wherein the needle holder has an elongated body with a needle holding portion in front and a head in back. The head of the needle holder has a cooperating outwardly facing surface configured to cooperate with said inwardly facing surface along an interface oriented in the direction of retraction to produce a holding force on the needle holder when installed in the nose in the unretracted position. The needle holder and spring are easily installable from the rear of the barrel toward the nose and releaseably held by sliding engagement of said cooperating inwardly and outwardly facing surfaces while compressing the spring and thereby producing a holding force on the needle holder in opposition to the retraction force applied to

the needle holder by the spring. The parts are circular in cross section.

The outwardly facing surface on the circular head of the needle holder is slightly greater in diameter than the circular inward facing surface in the wall at the most constricted portion where the nose begins. The needle holder is thus clamped in position by hoop stresses induced in the outer body and held in position by frictional holding force. The needle holder is released in response to depression of the plunger to a retraction position. Retraction occurs in response to thumb force on the plunger when a portion of the plunger passing into the transition zone separates at least a portion of the inwardly and outwardly facing cooperating surfaces thereby reducing the holding force on the needle holder to an amount less than a retraction force on the needle holder produced by the spring whereby the needle holder is retracted into the cavity a distance sufficient to withdraw an injection needle, attached to the needle holder, into the outer body.

In one embodiment, the head of the needle holder is a two part head comprising an inner head surrounded by a separable retainer member wherein the outer surface of the retainer member is the outwardly facing surface with cooperates with the inwardly facing surface in the wall to retain the needle holder in an unretracted position at the most constricted part of the transition zone where the nose begins. The retainer member is a ring member coupled to the inner head along a sliding interface oriented in the direction of retraction with a friction force which exceeds the retraction force provided by the spring. The front of the needle holder is grounded in the nose portion against forward movement. The plunger head is configured to pass through the most constricted area and push against the retainer member without also pushing against the head of the needle holder.

The front of the plunger has an opening for a stopper slidingly fitted therein in an interference fit. The stopper is fitted in the opening in an interference fit along a sliding interface oriented in the direction of retraction. The stopper is mostly or fully dislodged by contact with the retraction mechanism at the end of an injection cycle by continued depression of the plunger from a first position at the end of the injection cycle to a second position with the tip of the plunger in contact with the retainer ring. This avoids cumulation of the force on the plunger required to dislodge the stopper from the opening and the force required to dislodge the retainer member from the head of the needle holder and outer body wall. Upon further depression of the plunger from the second position to the retraction position, the frictional holding force on the needle holder is reduced until the retraction force provided by the spring exceeds the remaining holding force and the needle holder and needle connected thereto are ejected into the cavity carrying the dislodged stopper along with them. The dislodging of the stopper and the retainer member alone make the syringe non-reusable. The plunger cannot be removed after retraction because the graspable end cap enters an opening at the back of the barrel when the plunger is depressed to the retraction position to prevent tampering after retraction.

The syringe has a high blowout pressure and a low plunger thumb force required to cause retraction. Blowout pressure is the fluid pressure operating on the stopper and retainer ring during an actual injection, High blowout pressure resistance is obtained because the retainer ring is mounted in the most constricted potion of the barrel where the nose begins which significantly reduces the amount of area exposed to fluid pressure. The smaller retainer ring allows the use of a small needle holder such that the opening in the plunger and the stopper can be only a fraction of the cross sectional area of the fluid chamber below the plunger head. The ratio of the greatest cross sectional area of the variable chamber and that of the dislodgeable stopper or the ring member are selected so that the maximum expected thumb force on the plunger during an injection will produce a maximum pressure in the chamber which will generate a blowout force on the stopper and retainer member slightly less than the amount of dislodging force necessary to dislodge the stopper and retainer member during retraction. This ratio should be at least two to one, or more preferably three to one or more, in order to ensure against premature blowout of the stopper or retainer ring.

In an alternate embodiment, the fewest number of easily made separate parts are used in a retractable syringe. The alternate embodiment has a similar stopper in the head of the plunger and a similar needle holder and spring combination with mating cooperating inwardly facing and outwardly facing interengaged surfaces at the most constricted part of a transition zone where the nose begins. In the alternate embodiment, there is no retainer ring around the head of the needle holder. Instead a tiny ramp is provided at the transition zone or adjacent the transition zone whereby the head of the plunger gently spreads the barrel outwardly while dislodging the stopper thereby reducing the clamping or friction force on the head of the needle holder provided by the wall of the outer body. The holding force is thereby reduced below the retraction force provided by the compressed spring and the needle holder is ejected into the cavity of the plunger carrying the dislodged stopper along with it.

Manufacture and assembly is facilitated by the fact that the plunger and the outer body can be molded with a non-collapsible core tool that can be pulled out from behind. The parts are simply shaped and do not have hooks and parts with reentrant angles that require collapsible core pin technology. The outer body can be made in one piece and assembled from the rear. The narrowed nose portion provides no lateral space with will permit bunching of the spring and jamming when the retraction assembly is moved forward in the outer body. In fact, the nose serves as a guide to steer the parts into the proper position in one smooth stroke.

The needle does not have to be installed before the retraction mechanism is put in place because it is readily installed from the front after the needle holder is slidingly lodged in the nose. Significant variations in the holding force on the needle holder and the dislodging force on the stopper due to slight variances in the tolerance of the mating parts is avoided because the longitudinal wall of the outer body has some flexibility. The wall can spread outwardly slightly and the stopper and head of the needle holder can compress slightly radially and expand slightly in the longitudinal direction to avoid significant changes in the holding force caused by small changes in the actual diameters. Consistency in the amount of retraction force is thereby provided and economy is assured.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross section along the central axis of a first embodiment of the invention with the plunger positioned in a first position at the end of an injection cycle;

FIG. 2 is the syringe of FIG. 1 with the plunger depressed additionally to dislodge the stopper at a second position of the plunger wherein the tip of the plunger is ready to operate the retraction mechanism;

FIG. **3** is the syringe of FIG. **2** wherein the plunger has been further depressed to a retraction position, retraction has occurred and the cap at the back of the plunger is closely received in an opening at the back of the outer body;

FIG. **4A** is a partial cross section on the central axis of an alternate tamperproof opening in the back of the outer body prior to retraction;

FIG. **4B** is the structure of FIG. **4A** with the plunger in the retracted position received in an opening at the back of the outer body;

FIG. **5** is a cross section along the central axis of a simplified alternate syringe structure without a retainer member around the needle holder, which is released by separation of the friction surfaces, shown in the plunger position which represents the end of an injection cycle;

FIG. **6** is the syringe structure of FIG. **5** wherein the plunger is further depressed to dislodge the stopper and begin to release the friction surfaces just prior to retraction;

FIG. **7** is the syringe structure of FIG. **6** with the plunger further depressed beyond the position of FIG. **6** to the retraction position where retraction has occurred and the cap is secure within an opening in the back of the hollow outer body.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the description that follows, like parts will be referred to by the same reference numerals. The drawings are enlarged significantly in order to show the details of the invention but generally reflect the true scale which is contemplated. The parts as shown are understood to be preferably circular and symmetrical as is conventional for syringes. The drawings reflect a syringe structure having a 1 cc to 3 cc injection fluid capacity.

FIG. **1** shows the structure of the first embodiment generally referred to by reference numeral **10**. Syringe **10** has a one piece hollow outer body **12**. Body **12** has a longitudinally extending wall comprising an elongated barrel **14** and a nose **16** with a transition zone **18** connecting the barrel and nose. A front mounted retraction mechanism lodged in the nose is generally referred to by the reference numeral **20**. It comprises the combination of an elongated needle holder **22** and spring **24**. The needle holder has an elongated body with a needle holding portion **26** in front for holding a needle **28** and a head **30** in back. Head **30** may consist of a two part head as in FIGS. **1–3** or a one part head as in FIGS. **5–7**. The needle holder is released by depression of a plunger that will be described.

A plunger generally designated by the reference numeral **32** is disposed for use partially within barrel **14**. The plunger has a head and seal generally referred to by reference numeral **34**, in slidable sealed contact with the interior of barrel **14** of outer body **12**. The plunger has a seal element **36** that is conventional and a retraction cavity **38** therein.

Head **34** has a tip portion **40** forming an opening **41** into retraction cavity **38**. A resilient dislodgable stopper **42** is sealingly positioned in opening **41** with a front portion thereof extending beyond tip **40**. Head portion **34** and the back part of stopper **42** have cooperating lands **44**, **46**, respectively, which seal opening **41**. Plunger **32** has an end cap **48** for depression of the plunger by the thumb. End cap **48** has a central opening for permanently receiving force fit plug **50** to close retraction cavity **38** at the back end.

A plurality of longitudinally extending flutes **52** slidingly support plunger **32** in barrel **14**. In the embodiment of FIG. **1**, outer body **12** has a collar **54** extending behind finger grips **56** having opening **58** which closely receives the outer periphery **60** of cap **48** when the plunger is depressed to the retracted position. An alternate arrangement is shown in FIGS. **4A** and **4B** in which barrel **14** is extended longitudinally, if necessary, so that end cap **48** fits closely within an opening at the back of the barrel where the finger grips are. FIG. **4B** shows the tamperproof position with the plunger in the retracted position. It should be noted that depending on the relationship of the inside diameter of the barrel and the diameter of the end cap, the end cap could instead be received right inside the opening at the back of the barrel. Regardless of how the end cap in back of the outer body and barrel are configured, the plunger can no longer be grasped after retraction has occurred because end cap **48** is depressed into an opening.

The wall of outer body **12** and head **30** of the needle holder have mating cooperating smooth surfaces which hold needle holder **22** in the position shown in FIG. **1** with spring **24** compressed. Nose **16** has a reduced diameter relative to the barrel. The outer body has a most constricted part where head **30** of needle holder **22** is engaged and held. The outer body has an inwardly facing surface **62** at the most constricted part of the transition zone where nose **16** begins. Similarly, head **30** has an outwardly facing surface **64** configured to cooperate with inwardly facing surface **62** to produce a holding force on needle holder **22** when the retraction mechanism is installed in the nose from the rear. Mating surfaces **62**, **64** constitute a sliding interface oriented in the direction of retraction, which seals nose **16**. Mating surfaces **62**, **64** are preferably friction surfaces which have an interference sliding fit to apply a frictional holding force which holds needle holder **22** in position by friction between the mating parts. It is within contemplation of the invention that one or more of the cooperating interface surfaces could employ a coating or adhesive bond which is ruptured or released when the mating surfaces or lands are separated or moved relative to each other.

Head **30** provides a lower boundary for a variable fluid chamber **68** below head **34**. Needle holder **22** has a fluid path **70** in fluid communication with fluid chamber **68** and needle **28**. Needle holder **22** has a smaller diameter inner head **72** which is part of head **30**. Retainer member **66** is coupled to inner head **72** along sliding interface **74** oriented in the direction of retraction. Retainer member **66** is coupled to inner head **72** with a holding force which exceeds a retraction force applied to the underside of inner head **72** by means of the end of compressed spring **24**. A reduced diameter portion **27** of needle holder **22** protrudes through an opening in front **76** of nose **16**.

Importantly, retainer member **66** can be visualized as an annular ring surrounding circular inner head **72**. The location of retainer member **66** at the most constricted part of the transition zone where the nose begins and the relatively small area exposed to pressurized fluid in chamber **68** results in a high blowout pressure. Since the front portion **26** of the needle holder is grounded or bottomed inside front **76** of nose **16**, no amount of pressure will allow needle holder **22** or needle **28** to move forward. Blowout pressure may be defined as the pressure in chamber **68** acting on the exposed area of retainer member **66** to produce a force sufficient to overcome the holding force such that retainer **66** could "blowout" by moving forward and prematurely release needle holder **22**.

Some users have strong hands and might, at the outer limit in an emergency, be able to generate a force of as much as fifteen to eighteen pounds on the plunger during an injection.

It is considered almost impossible for anyone to exert a force of more than eighteen pounds. This may be regarded as the maximum expected force which must be taken into account so that ring member **66** will not blowout while an injection is being made. The greatest cross sectional area of variable chamber **68** and the area of retainer member **66** exposed to fluid pressure are selected so that the blowout pressure is higher than the maximum pressure in chamber **68** expected to result from the maximum expected thumb force applied to cap **48** during an injection. This ratio is preferably about two to one and more preferably about three to one or more so that the holding force holding the retraction mechanism in place can be kept at a comfortably low level while the blowout pressure remains high.

Dislodgeable stopper **42** has a similar blowout problem to recognize. The front and middle portion of stopper **42** are relieved slightly from opening **41** such that the fluid pressure in chamber **68** is directed against the cross sectional area at cooperating lands **44**, **46** and could cause stopper **42** to blowout. A frictional holding force is generated at the lands **44**, **46** which may be called a dislodging force which must be overcome to slide stopper **42** rearwardly before retraction. The ratio of the maximum cross sectional area across the interior of variable chamber **68** to the maximum cross sectional area of stopper **42** exposed to pressure in chamber **68** are selected so that the maximum expected thumb force on plunger **32** during an injection will produce a maximum force slightly less than the amount of dislodging force necessary to dislodge the stopper so that stopper **42** will not blowout during an injection. This ratio is preferably not less than about two to one, more preferably three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds, respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The stopper is dislodged after the injection by thumb force applied to the stopper by movement of the plunger.

The components used for retraction are arranged to avoid cumulation of force during the retraction sequence. In FIG. **1**, stopper **42** has a forward extension beyond tip **40** which allows full thumb pressure to be applied to the stopper before any other portion of the retraction mechanism is engaged. The amount of forward extension beyond tip **40** is related to the length of lands **44**, **46** such that the forward extension of stopper **42** preferably represents about 80 percent of the engaged land length. When stopper **42** is moved back until the front is even with tip **40**, as seen in FIG. **2**, only about 20 percent of engaged land remains. In FIG. **2** it can be seen that thumb force on plunger cap **48** has been applied to partially dislodge stopper **42** such that a gap **78** is created and the remaining engaged land area is represented as area **80**.

Since I believe the amount of frictional holding force or dislodging force is roughly proportional to the amount of the length of the sliding interface between cooperating lands **44**, **46**, it follows, ignoring dynamic effects, that the amount of force remaining decreases as the engaged sliding interface area is reduced. This is what happens as stopper **42** moves back into cavity **38** from the position of FIG. **1** to the position of FIG. **2**. It is believed appropriate to set the initial dislodging force to allow about five pounds at the position of FIG. **1** which is reduced to about one pound remaining when the plug member reaches the position of FIG. **2**. It might be noted at this point in the description that the front portion of tip **40** preferably has some longitudinally extending slits or openings so that fluid is not trapped in the trapezoidal shaped area of chamber **68**, seen in FIG. **2**, because of contact between tip **40** and the upper surface of retainer ring **66**.

Needle holder **22** and spring **24** are combinably installable from the rear of the barrel before the plunger is assembled and releasably held at the most constricted part of the transition zone where the nose begins by sliding engagement of the cooperating inwardly and outwardly facing friction surfaces **62**, **64** while compressing spring **24**. The length of the engaging land **64** and the amount of interference fit is preferably designed to provide a frictional holding force in opposition to the retraction force provided by the compressed spring **24** of somewhere around five pounds even though the spring may apply a retraction force in the retraction direction of somewhere around a half pound. In use the needle is pushed against a rubber seal in a vial so the needle holder must resist a resulting backward force without being dislodged during the filling operation. This requirement and blowout pressure limits the low end of the holding force on the needle holder.

Referring again to FIG. **2**, it can be seen that further depression of the plunger beyond the second position of FIG. **2** dislodges retainer ring member **66** along the sliding interface **74** provided by the outer surface of inner head **72** and along the inwardly facing friction surface **62**. As the amount of remaining engaged interface is reduced, the amount of force required to continue moving retainer member **66** off needle holder **22** is reduced and the small remaining engagement area **80** between lands **44**, **46** of the plunger and stopper preferably cause stopper **42** to be dislodged before needle holder **22** is released. When the remaining residual friction force during continued depression of the plunger becomes less than the retraction force provided by compressed spring **24**, the retraction position of FIG. **3** is reached whereby retraction occurs.

When retraction occurs needle holder **22** moves through opening **41** into cavity **38**. The uncompressed length of spring **24** is selected to provide backward movement sufficient to withdraw an injection needle **28** fixed in front portion **26** entirely within outer body **12**, carrying dislodged stopper **42** with it. At the same time, cap **48** enter opening **58** of the barrel with peripheral edge **60** closely confined, in order to prevent tampering after retraction. It is immaterial whether cap **48** moves into the opening at the instant of retraction or after retraction has already occurred because the movement is automatic due to the continued thumb force applied to trigger the retraction. Sufficient unengaged length of inwardly facing friction surface **62** is provided so that retainer member **66** can move downwardly a sufficient distance to reach the retraction position of FIG. **3**. After retraction, retainer member **66** preferably remains stuck and prevents any possibility of any one being able to reengage it with the head of needle holder **22**. The diameter of land **62** in the area designated **63** can be increased slightly to provide relief for retainer ring **66** as it is pushed down by tip **40**.

An alternate syringe **82** is disclosed in FIGS. **5–7**. In FIG. **5**, Syringe **82** has a one piece hollow outer syringe body **84**. Body **84** has a longitudinally extending wall comprising an elongated barrel **86** and a nose **88** with a transition zone **90** connecting the barrel and nose. A front mounted retraction mechanism lodged in nose **88** is generally referred to by the reference numeral **92**. It comprises the combination of an elongated needle holder **94** and spring **96**. The needle holder has an elongated stem body with a needle holding portion **100** in front for holding needle **28** and a head **102** in back. In this case, head **102** is a one part head integral with the rest

of needle holder **94**. Spring **96** delivers a retraction force in a retraction direction to the underside of head **102**.

A plunger generally designated by reference numeral **104** is disposed for use partially within barrel **86**. Plunger **104** has a head portion **106** which moves in slidable sealed contact with the interior of barrel **86** of outer body **84**. Although a separate seal might be used on head **106**, this embodiment is suitable for a smaller diameter, such as a 1 cc syringe, and can be used with head **106** also serving as the seal. A retraction cavity **108** is provided in the interior of hollow plunger **104**. Head **106** has a tip portion **110** forming an opening **112** for a dislodgable stopper **114** having a front portion extending beyond tip **110**. Head portion **106** has an inwardly facing land **116** and the back of stopper **114** has an outwardly facing land **118** comprising cooperating friction surfaces which seal opening **112**. The back portion of outer body **84** may have finger grips **120** and the same collar **54** and end cap **48** previously disclosed. The alternate arrangement of FIGS. 4A and 4B may also be employed.

The outer portion of tip **110** may be equipped with an angled surface **122** designed to cooperate with a small ramp surface **124** located in the vicinity of transition zone **90**. The wall of outer body **84** and head **102** of the needle holder have mating cooperating friction surfaces which frictionally hold needle holder **102** in the position shown in FIG. **5** with spring **96** compressed. Nose **88** has a reduced diameter relative to barrel **86**. The outer body has a most constricted part where the head **102** of needle holder **94** is frictionally engaged. The outer body has an inwardly facing surface or land **126** at the most constricted part of the transition zone where nose **88** begins. Similarly, head **102** has an outwardly facing friction surface **128** configured to cooperate with inwardly facing surface **126** to produce a frictional holding force on needle holder **94** when the retraction mechanism is installed in the nose from the rear.

Mating surfaces **126**, **128** constitute a sliding interface oriented in the direction of retraction, which seal nose **88**. Mating surfaces **126**, **128** are preferably smooth friction surfaces which have an interference sliding fit when needle holder **94** is installed from the rear whereby a frictional holding force holds needle holder **94** in position by friction between land **126** and head **102** of needle holder **94**. It is within contemplation of the invention that one or both of these surfaces could have a coating or adhesive bond which is ruptured when the mating surfaces are separated to release the needle holder.

Head **106** provides the upper boundary for a variable fluid chamber **130** below head **106**. Needle holder **94** has a fluid path **132** in fluid communication with chamber **130** and needle **28**. Needle holder **94** is releasably coupled at surfaces or lands **126**, **128** with a holding force that exceed the retraction force applied to the underside of head **102** by the end of compressed spring **96**. A reduced diameter portion **134** of needle holder **94** protrudes through an opening in front **136** of nose **88**. Blowout pressure is not a factor with respect to the needle holder on the alternate embodiment. No amount of pressure will allow needle holder **94** or needle **28** to move forward since the front portion **100** of the needle holder is grounded or bottomed inside front **136** of nose **88**.

Blowout pressure is still a factor to be considered in connection with stopper **114**. Blowout pressure would be the pressure in chamber **130** produced by thumb force on cap **48** acting on the cross sectional area of stopper **114** which could overcome the holding force, causing stopper **114** to dislodge from opening **112** prematurely. The ratio of the maximum cross sectional area across the interior of variable chamber **130** to the maximum cross sectional area of stopper **142** exposed to pressure in chamber **130**, and the dislodging force necessary to dislodge stopper **144**, are selected so that the maximum expected thumb force on plunger **104** during an injection will not cause the stopper to blowout. Yet the stopper will still be dislodged by the dislodging force on the plunger once the front of stopper **114** contacts the retraction mechanism after the injection has ended. The ratio referred to is preferably not less than about two to one, or more preferably about three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The smaller diameter stopper allows two or three times the thumb force to be used during the injection cycle than required to actually dislodge the stopper by direct application of force.

By reference to FIGS. **5–7**, the operation and further features of the alternate embodiment are discussed. The syringe is used in the normal manner until the plunger is depressed to the first position of FIG. **5** which is the end of the injection cycle. Stopper **114** has a forwardly extending end which has come into contact with head **102** of needle holder **94** to block fluid path **132**. Further depression of plunger **104** toward the position of FIG. **6** mostly or fully dislodges stopper **114** and begins spreading barrel **84** at the transition zone by sliding contact between head portion **106** and ramp **124**. Ramp **124** is a very small inwardly extending annular thickening of the wall of barrel **86** which can take many shapes or forms. For example, ramp **124** may be a small step **125** in the wall which continues vertically downward as indicated by the dotted line, which is somewhat exaggerated in FIG. **5**.

The barrel is flexible and is spread outwardly a slight amount to the position of FIG. **6** just prior to retraction. Here the mating surfaces **126**, **128** are separated an amount which reduces the clamping force on the needle holder **94**. The spreading shown in FIG. **6** is greatly exaggerated for illustration. It is estimated that an expansion of only about four thousandths of an inch is sufficient to release needle holder **94** from nose **88**. By slight further depression of the plunger from the position of FIG. **6** to the retracted position of FIG. **7**, retraction occurs when the retraction force applied by spring **96** exceeds the remaining holding force on needle holder **94**. Needle holder **94** then moves through opening **112** into cavity **108** along with a portion of spring **96**. The uncompressed length of spring **96** is designed to provide sufficient backward movement to withdraw an injection needle **28** fixed in front portion **94** and carry dislodged stopper **114** with it. At the same time, cap **42** enters opening **138** at the rear of a barrel extension **54** where the peripheral edge is closely confined in order to prevent tampering after retraction.

The location and configuration of ramp **124** is arranged to avoid cumulation of force required during the retraction sequence. Most of stopper **114** should be dislodged by thumb pressure on plunger **104** before significant resistance develops as angled surfaces **122** begin pushing outwardly on ramp **124**. The selection of the location of ramp **24** and the angle of the engaging surfaces make it possible to have a fairly smooth continuous force since the dislodging force continuously decreases as the sliding interface area **116**, **118** between the plunger and the stopper is linearly decreased. Because ramp **124** is relatively very small, it is still possible to remove a stepped molding core from the rear of the outer

body **84**. Alternately, ramp **124** can be the smaller diameter step **125** which avoids reentrant angles whereby resistance to removal of the molding core could occur. After retraction, the back of the plunger is unaecessible and there is no way to reach to stopper or the needle holder in order to reinstall them for re-use.

In operation, there are many advantages to the improved combination disclosed herein. The diameter of the stopper in both embodiments and the slidable retaining ring member in the first embodiment, in relation to the diameter across the fluid chamber, makes it possible to produce a syringe which withstands high blowout pressure. By minimizing the effective surface area exposed to the pressurized fluid during an injection, the syringe will withstand injection thumb force of around fifteen to eighteen pounds during injection and at the same time retract in response to as little as five to six pounds of force on the plunger once the injection fluid has been injected. Once the fluid has been injected, cumulation of force required to concurrently operate the retraction mechanism is avoided. First the stopper is moved back and then the needle holder is released. By constricting the diameter of the syringe near a transition zone where the nose begins, a constriction enables the needle holder to be smaller which in turn allows it to fit in a smaller opening with a smaller stopper in the retraction cavity of the hollow plunger.

A vacuum must be pulled in order to fill the syringe. The ring member or the needle holder, as the case may be, must seal the front nose of the syringe body because otherwise vacuum could be lost and fluid could enter the spring area and leak out the front. The hollow outer body and syringe plunger are preferably made from conventional plastic material used for syringes, which has some flexibility. The tolerances on the diameter of mating facing surfaces between the head of the needle holder and the barrel and between the stopper and head of the plunger are not critical in order to maintain a consistent holding and dislodging force. This is believed to be because increasing interference fit increases the frictional holding force only up to a point and then the surrounding wall simply expands a small amount or the internal parts are compressed a small amount without a corresponding increase in the longitudinal force required to move the retainer member or plug member in the retraction direction. It is a desirable self correcting mechanism which is a cost and quality benefit in making the parts. It is believed that a plastic retainer member could be used and the same self limiting frictional holding force would be obtained.

In the best mode the stopper and the ring member are preferably made from a thermoplastic rubber material designated number 181-55 available from Advanced Elastomer Systems, 540 Maryville Centra Drive, St. Louis, Mo. and sold under the trade name Santoprene®. It is said to have a characteristic hardness around 55 on the Shore A durometer scale which allows for the right amount of resistance to compression, fluid resistance such that the material does not swell when in contact with most fluids, environmental stability allowing the friction and sealing properties to remain non-temperature sensitive, good property retention after aging and excellent property retention after sterilization by all accepted methods. The plunger seal around the head of the plunger is conventional.

The parts are few in number and easily mass produced. The alternate embodiment has the fewest number of separate parts of any tamperproof retractable syringe. The plunger has a one piece hollow outer body with a transition zone and a narrow nose portion. The internal diameter is stepped to greater diameters from front to back for molding around a non-collapsible core which can be extracted from the rear. The same is true for the plunger.

Assembly is greatly simplified and can be accomplished with high speed mechanized equipment. The needle holder and spring are installable from the rear of the barrel without the needle. In the first embodiment the retainer member is forced fit over the inner head of the needle holder and the assembly together with the uncompressed spring are pushed forward and held by sliding engagement of the cooperating inwardly and outwardly facing surfaces while compressing the spring. The front of the needle holder passes through an opening in the nose which makes it easy to install the needle from the front by conventional means. The alternate embodiment is installed the same way except that there is no separable retainer member around the head of the needle holder.

The narrow nose provides a particular advantage for mechanized assembly. The nose has a wall defining an elongated internal cavity which closely confines the spring and needle holder combination. During installation this cavity serves as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring. This solves an important assembly problem. If there is much lateral space in the nose around the spring, when the uncompressed spring is being compressed, it is a laterally unstable column which flexes sideways and bunches up causing a jam up. It might be added that rounded edges on the bottom of the slot directly below retainer **66** would further facilitate entry of the end of the spring.

The stopper is also installable from the rear of the plunger by pushing it forward until the cooperating lands are slidingly engaged. Then plug member **50** is force fit or otherwise fixed in the opening at the back of the plunger and the plunger is installed in the outer body. It is not necessary to try to pass the sharp needle through an elongated body with constricted openings where slight misalignment could cause hangups. The head of the needle holder simultaneously acts as a seal as well as a holding device such that no seal is required at the tip of the nose and no ultrasonic welding of separate parts is required.

There is no necessity for using internal locking teeth of any kind. No locking teeth are needed to hold the retraction mechanism or to lock the plunger after retraction. Locking teeth present difficult molding and quality control problems, tend to be temperature sensitive and tend to require a larger diameter barrel which increases premature blowout problems. In addition to the non-reusability provided by separation of the retainer ring from the head of the needle holder and dislodgement of the stopper, the plunger is not accessible after retraction because it is depressed within an opening at the back of the outer body. This additional tamperproof feature is provided in a one piece body without the necessity for hooking anything or twisting anything. The easily made and installed force fit plug at the back of the retraction cavity prevents access to the retracted components. The Federal government has fights in the invention under 35 U.S.C. §203. The Federal government has a nonexclusive, nontransferable irrevocable, paid up license to the invention.

I claim:

1. A tamperproof retractable syringe for injecting fluid wherein the syringe has a one piece body and a frictionally held retraction mechanism assembleable from the rear which is retractable with low plunger force and resists high blowout pressure during an injection, comprising:

a one piece hollow outer body having a longitudinally extending wall, comprising an elongated barrel and

nose, with a transition zone connecting the barrel and nose, the nose having a reduced cross sectional area relative to the barrel and an inwardly facing surface in the wall at the most constricted part of the transition zone where the nose begins;

a plunger assembly disposed partially within the elongated barrel, the plunger having a head in slidable sealed contact with the interior of the outer body and a retraction cavity therein for receiving parts of a retraction mechanism;

a retraction mechanism comprising an elongated needle holder and spring combination wherein the needle holder is released by depression of the plunger to a retraction position, the needle holder having an elongated body with a needle holding portion in front and a head in back, having a cooperating outwardly facing surface configured to cooperate with said inwardly facing surface to produce a holding force on the needle holder when the retraction mechanism is installed in the nose;

the needle holder and spring being installable from the rear of the barrel toward the nose and releaseably held by sliding engagement of said inwardly and outwardly facing surfaces while compressing said spring, said sliding engagement producing said holding force in opposition to a retraction force applied to the needle holder by said spring;

retraction occurring in response to thumb force on the plunger when a portion of said plunger passing into said transition zone causes the cooperating outwardly facing surface to slide relative to said inwardly facing surface and thereby reduces the holding force on the needle holder to an amount less than the retraction force whereby the needle holder is retracted into said cavity a distance sufficient to withdraw an injection needle into the outer body.

2. The tamperproof retractable syringe of claim **1** wherein the inwardly facing surface in the wall and the cooperating outwardly facing surface on the needle holder are friction surfaces which cooperate to produce said holding force on said needle holder as a frictional holding force.

3. The tamperproof retractable syringe of claim **2** wherein said frictional holding surfaces comprise a linear interface aligned in the direction of retraction.

4. The tamperproof retractable syringe of claim **1** wherein the plunger has a graspable end cap for depressing the plunger and a length selected to allow the end cap to enter an opening of the barrel when the plunger is depressed to the retraction position, in order to prevent tampering after retraction.

5. The tamperproof retractable syringe of claim **1** wherein the needle holder and the most constricted part of the transition zone where the nose begins comprise a lower boundary of a variable fluid chamber below the plunger head and the needle holder has a fluid path for injection fluid opening into the variable chamber.

6. The tamperproof retractable syringe of claim **5** wherein the plunger head has a tip with an opening sealingly closed by a dislodgeable held stopper which slides relative to the plunger in response to dislodging force applied by depression of the plunger at the end of the injection cycle before retraction occurs.

7. The tamperproof retractable syringe of claim **6** wherein at the end of the injection cycle a forward end of the dislodgeable stopper comes in contact with the needle holder to block said fluid path whereby said dislodging force is applied during continued depression of the plunger prior to retraction.

8. The tamperproof retractable syringe of claim **7** wherein the ratio of the greatest cross sectional areas of the variable chamber and the dislodgeable stopper is selected so that the maximum expected thumb force on the plunger during an injection will produce a maximum pressure in the chamber which will generate a force on the stopper slightly less than the amount of dislodging force necessary to dislodge the stopper so that the stopper will not blowout during an injection.

9. The tamperproof retractable syringe of clam **8** wherein said ratio of the area of the variable chamber to the area of the dislodgeable stopper is at least two to one so that at least twice the force necessary to dislodge the stopper can be applied to the plunger during an injection without blowout of the stopper.

10. The tamperproof retractable syringe of claim **6** wherein said nose has a wall defining an internal cavity which closely confines the spring and needle holder combination and serves as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring to facilitate assembly from the rear without jamming.

11. The tamperproof retractable syringe of claim **10** wherein the front of the nose is provided with an opening and the front needle holding portion of the needle holder extends outwardly through said opening in order to facilitate installation of a needle from the front of the syringe after the needle holder has already been assembled in the nose.

12. The tamperproof retractable syringe of claim **1** wherein the head of the needle holder is coupled to a separable retainer member, along a sliding interface oriented in the direction of retraction, with a holding force which exceeds said retraction force, the outer surface of said retainer member having said outwardly facing surface configured to cooperate with said inwardly facing surface to produce said holding force on the needle holder when the retraction mechanism is installed in the nose.

13. The tamperproof retractable syringe of claim **12** wherein said ratio of the greatest cross sectional area of the variable chamber to the area of the retainer member exposed to fluid is selected so that the retainer member has a high blowout pressure higher than the maximum pressure expected, as a result of maximum expected thumb force on the plunger and a low frictional holding force to be overcome during retraction so that the thumb force required to trigger retraction is comfortably and substantially lower than said maximum thumb force expected.

14. The tamperproof retractable syringe of claim **13** wherein the ratio of the greatest cross sectional area of the variable chamber to the cross sectional area of the retainer member exposed to fluid in the variable chamber is not less than about two to one so that high blowout pressure can be resisted while retaining a relatively low force on the plunger necessary to cause retraction.

15. The tamperproof retractable syringe of claim **2** wherein the head of the needle holder is a two part head comprising a head surrounded by a separable retainer member coupled with a friction force which exceeds said retraction force along a sliding interface oriented in the direction of retraction, the outer surface of said retainer member being said outwardly facing friction surface which cooperates with said inwardly facing friction surface to retain said needle holder in an unretracted position at the most constricted portion of the transition zone where the nose begins.

16. The tamperproof retractable syringe of claim **15** wherein the body of the needle holder is grounded in the nose portion against forward movement and the front of the plunger head is configured to pass through the said most

constricted area and push against said retainer member without also pushing against the head of said needle holder and thereby cause retraction.

17. The tamperproof syringe of claim **16** wherein the frictional holding force on the needle holder to be overcome by thumb force on the plunger during retraction is relatively low relative to the maximum expected force on the plunger during an injection, the retainer member having a reduced surface area exposed to fluid pressure in the variable chamber selected to resist blowout and premature retraction.

18. The tamperproof syringe of claim **17** wherein the ratio of the cross sectional area of the variable chamber to said reduced surface area of the retainer member exposed to fluid pressure in the variable chamber is not less than about two to one.

19. The tamperproof retractable syringe of claim **16** wherein the needle holder and the most constricted part of the transition zone where the nose begins comprise a lower boundary of a variable fluid chamber below the plunger head and the needle holder has a fluid path for injection fluid opening into the variable chamber.

20. The tamperproof retractable syringe of claim **19** wherein the plunger head has an opening sealingly closed by a dislodgeable frictionally held stopper which slides relative to the plunger in response to dislodging force applied by depression of the plunger at the end of the injection cycle before retraction occurs.

21. The tamperproof retractable syringe of claim **20** wherein the greatest cross sectional areas of the variable chamber and the dislodgeable stopper are selected so that the maximum expected thumb force on the plunger during an injection will produce a maximum pressure which will generate a force on the stopper slightly less than the amount of dislodging force necessary to dislodge the stopper so that the stopper will not blowout during an injection.

22. A tamperproof retractable syringe structure for injecting fluid into a patient comprising:

a syringe body having a wall forming an elongated barrel portion with a smaller nose portion in front and a transition zone between the barrel portion and the nose portion;

a moveable plunger in the barrel portion having a front end and a back end, the plunger having a head at the front end in sliding sealed contact with the interior of the barrel, a cap at the back end for applying thumb force to the plunger, and a cavity for receiving retractable parts;

a retraction mechanism disposed in the nose portion of the syringe body having retractable parts comprising a releasable needle holder and needle frictionally held by the wall of the syringe body with the needle extended from the nose portion, a biasing element applying a retraction force to the needle holder and a fluid path traversing the needle and needle holder;

the head of the plunger having an opening into said cavity, sized to receive the retractable parts and a releasable stopper extending from said opening, the stopper sealing the interior of the plunger from injection fluid stored in a variable chamber defined in the barrel between the retraction mechanism and the head of the plunger;

the plunger being depressible to a first position to expel injection fluid from the variable chamber through the fluid path in response to thumb pressure on said cap, said first position comprising the end of an injection;

said plunger being further depressible to a retraction position beyond the first position whereby said stopper is dislodged and said releasable needle holder is released from the syringe body and retracted into the cavity of the plunger a distance sufficient to withdraw said needle entirely within the syringe body;

said plunger being a length selected to remain graspable behind the barrel portion of the syringe body in the first position of the plunger and become ungraspable by withdrawal of the periphery of the cap within the syringe body in the second position of the plunger so that the retracted syringe cannot be tampered with.

23. The tamperproof retractable syringe of claim **22** wherein said syringe body is a one piece hollow body wherein said retraction mechanism is installable from the rear of the barrel toward the nose and releasably held by sliding engagement of cooperating inwardly and outwardly facing surfaces while compressing said spring.

24. The tamperproof retractable syringe of claim **23** wherein the nose closely confines the retractable parts comprising the needle holder and biasing element and serves to guide and steer them into position in the nose.

25. The tamperproof retractable syringe of claim **24** wherein the needle holder has an inner head and a separable :retainer member surrounding the inner head coupled along a sliding interface oriented in the retraction direction, said cooperating outwardly facing surface being the outer surface of said retainer member whereby said plunger is depressible to release said needle holder by sliding separation of said retainer member.

26. The tamperproof retractable syringe of claim **25** wherein the ratio of the greatest cross sectional area of the variable chamber to the area of the retainer member and to the area of the stopper exposed to fluid in the variable chamber are selected so that the maximum expected thumb force on the plunger during an injection will produce a pressure force on the stopper and retainer slightly less than the amount necessary to dislodge them so that they will not blowout during an injection.

27. The tamperproof syringe of claim **26** wherein said ratios are not less than two to one.

28. A tamperproof retractable syringe structure having low retraction force comprising:

a hollow syringe body having an elongated barrel portion extending between a nose portion adapted to support a needle holder and a rear portion having an opening for receiving a plunger from the back of the body;

an elongated plunger having a leading head end in front and a trailing back end provided with an end cap for pressing, the head end having an opening in front leading to a hollow cavity in the plunger extending rearwardly toward the back end, the head end being receivable through the opening in the rear portion of the syringe body and being movable in sliding sealed contact with the interior of the barrel;

a frictionally held dislodgeable stopper extending in sealing relation from the opening in the head end of the plunger whereby an upper boundary of a variable chamber for injection fluid is formed below the head of the plunger in the barrel of the syringe;

a needle holder and needle releaseably mounted in the nose portion of the syringe body with the needle extended, the needle holder having a elongated stem portion with a front end grounded against forward motion and a spaced apart enlarged head being releasably held in the nose portion of the syringe body by means of frictional force caused by constricting forces imposed thereon by the nose portion of the syringe

body, whereby a lower boundary of said variable chamber is formed above the enlarged head of the needle holder;

the needle holder and needle defining a fluid path for injection fluid opening into the variable chamber, said needle holder being sized to retract through said opening in the head end of the plunger;

a biasing element configured to apply a retraction force to the needle holder in said nose portion which is less than said frictional force, said biasing element having sufficient travel when unrestrained to carry the needle holder into the cavity of the plunger a distance sufficient to withdraw the extended needle within the syringe body when the needle holder is released from the nose portion of the syringe body;

the plunger being depressible in an injection stroke to expel injection fluid from the variable chamber until the plunger reaches a first position comprising the end of an injection stroke wherein the needle holder is encountered by the stopper;

said plunger being further depressible toward a retraction position whereby said stopper is being dislodged from said opening, the plunger reaching an intermediate position beyond said first position whereby further forward movement is effective to gradually remove the constricting forces holding the needle holder until said retraction position of the plunger is reached wherein said frictional force holding the needle holder becomes less than said retraction force applied by the biasing element and said needle holder is thereby released from said nose portion and retracted into said cavity.

29. The tamperproof syringe of claim **28** wherein the plunger length is selected to remain graspable by means of the end cap at the trailing end when the plunger is depressed to said first position, the plunger upon further depression to said second position, becoming ungraspable by passage of the end cap into the rear portion of the syringe body so that the retracted syringe cannot be tampered with.

30. The tamperproof syringe of claim **29** wherein the biasing element is a spring loosely surrounding the stem portion of the needle holder in close proximity thereof, the spring having a front end restrained by the nose portion of the syringe body and a rear end under the enlarged head of the needle holder.

31. The tamperproof syringe of claim **30** wherein said nose portion has a wall defining an internal cavity extended in the direction of retraction which closely confines the spring and thereby facilitates assembling from the rear the needle holder and uncompressed spring into a compressed state in said nose portion.

32. The tamperproof syringe of claim **32** wherein an opening is provided in the front of the nose portion of the syringe body and a part of the stem portion of the needle holder extends outwardly through said opening in order to facilitate installation of the needle into the stem portion of the needle holder from the front of the syringe after the needle holder has already been assembled in the nose portion of the syringe body.

33. The tamperproof syringe of claim **28** wherein the ratio of the cross sectional areas of the variable chamber and the dislodgeable stopper is selected so that the maximum expected thumb force on the plunger during an injection will produce a pressure force which is slightly less than the amount of force necessary to dislodge the stopper or cause it to move significantly with respect to the plunger opening.

34. The tamperproof retractable syringe of claim **33** wherein said ratio of the cross sectional areas of the variable chamber to the area of the dislodgeable stopper is at least two to one so that at least twice the force to dislodge the stopper can be applied to the plunger during an injection without blowout of the stopper.

* * * * *

EXHIBIT B

US005632733A

United States Patent [19]

Shaw

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[54] **TAMPERPROOF RETRACTABLE SYRINGE**

[76] Inventor: **Thomas J. Shaw**, 1510 Hillcrest, Little Elm, Tex. 75068

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[58] **Field of Search** 604/195, 192, 604/110, 187, 198, 263

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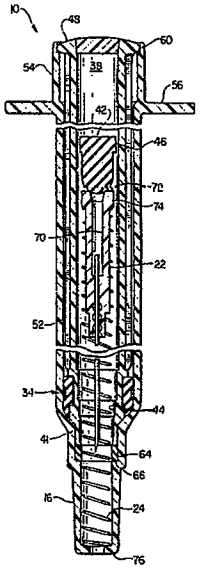
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Harris, Tucker & Hardin, P.C.

[57] **ABSTRACT**

A tamperproof retractable non-reusable syringe has a one piece hollow outer body with a barrel for a slidable plunger, a transition zone and a smaller diameter nose portion. An elongated needle holder and spring combination is installable from the rear of the outer body, guided into the nose portion and held by cooperating inwardly and outwardly facing surfaces oriented in the direction of retraction at the most constricted part of the transition zone where the nose begins. The plunger has an opening with a dislodgable stopper for receiving parts of the retraction mechanism. The stopper and the head of the needle holder are of significantly reduced diameter from the injection fluid chamber to resist blowing out prematurely. In one embodiment the head of the needle holder is surrounded by a separable retainer member which is slidingly removed by contact with the tip of the plunger after the stopper is mostly or fully removed to avoid cumulation of force required for retraction after the injection. In a second embodiment the head of the needle holder is clamped and held by constricting forces imposed by stress on the outer body induced by interference fit. Release occurs by slight expansion on the barrel by contact of the plunger tip with a small internal ramp in the outer barrel. Both embodiments have a plunger cap configured to enter an opening in the outer body to provide an additional tamperproof feature.

36 Claims, 5 Drawing Sheets



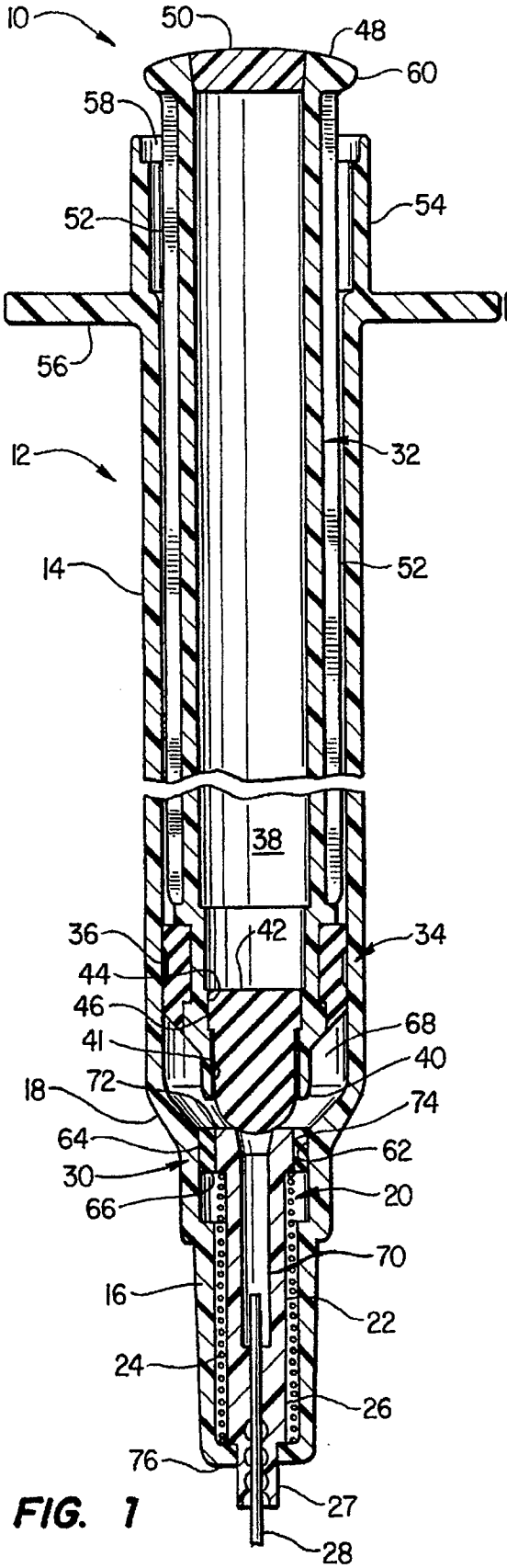

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FIG. 1

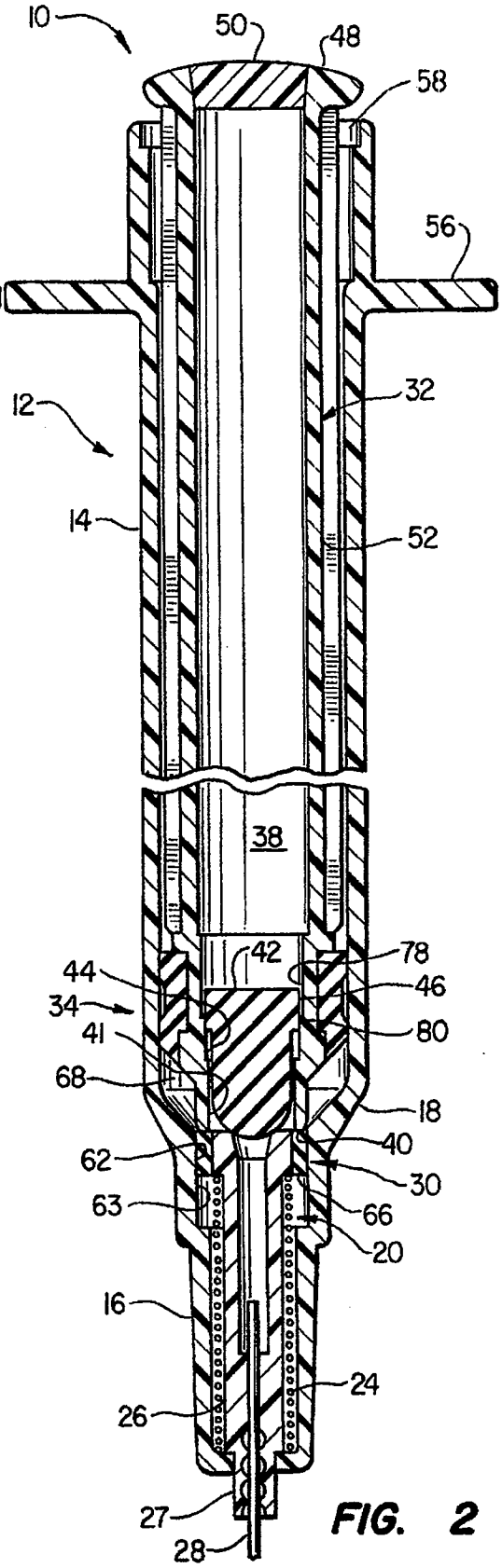
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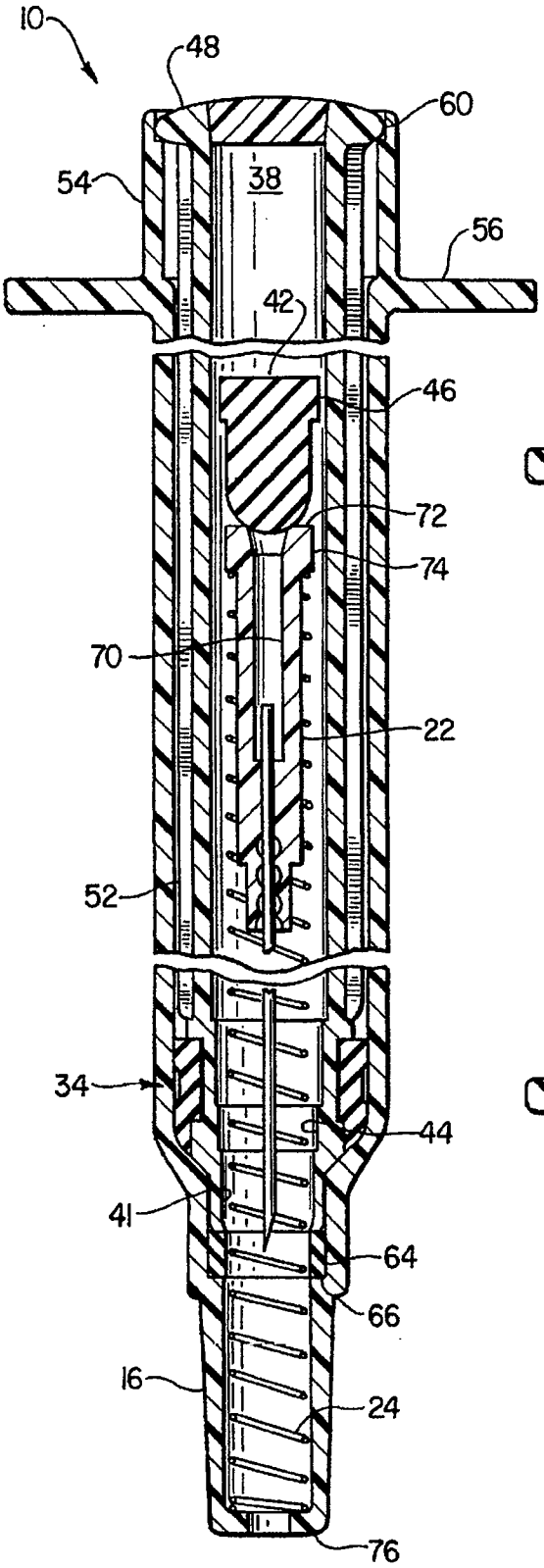
FIG. 2



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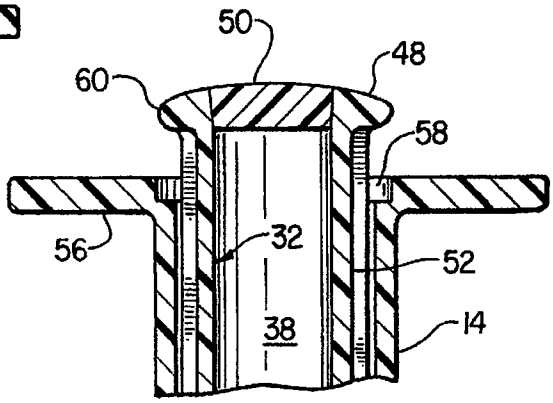

FIG. 4A

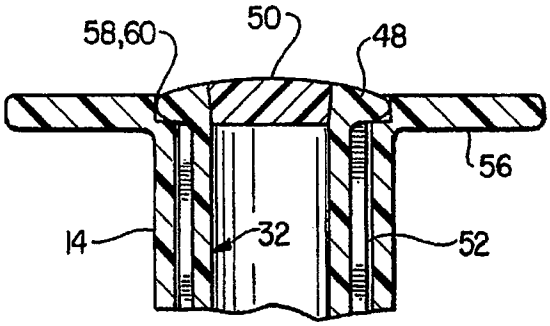

FIG. 4B

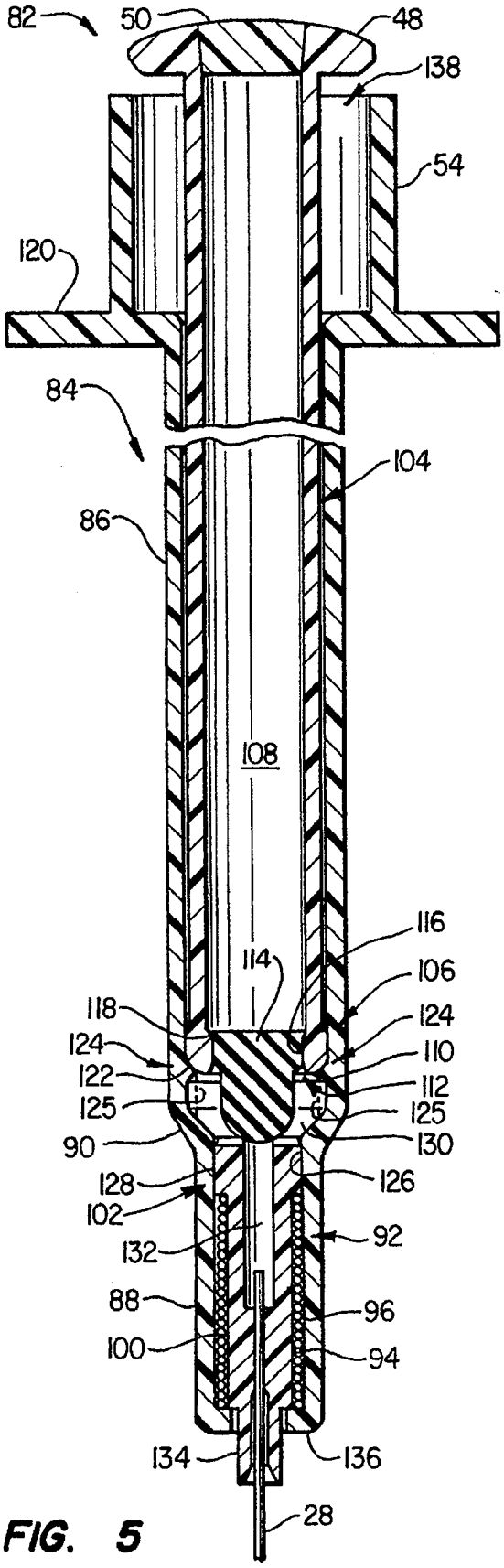
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FIG. 5

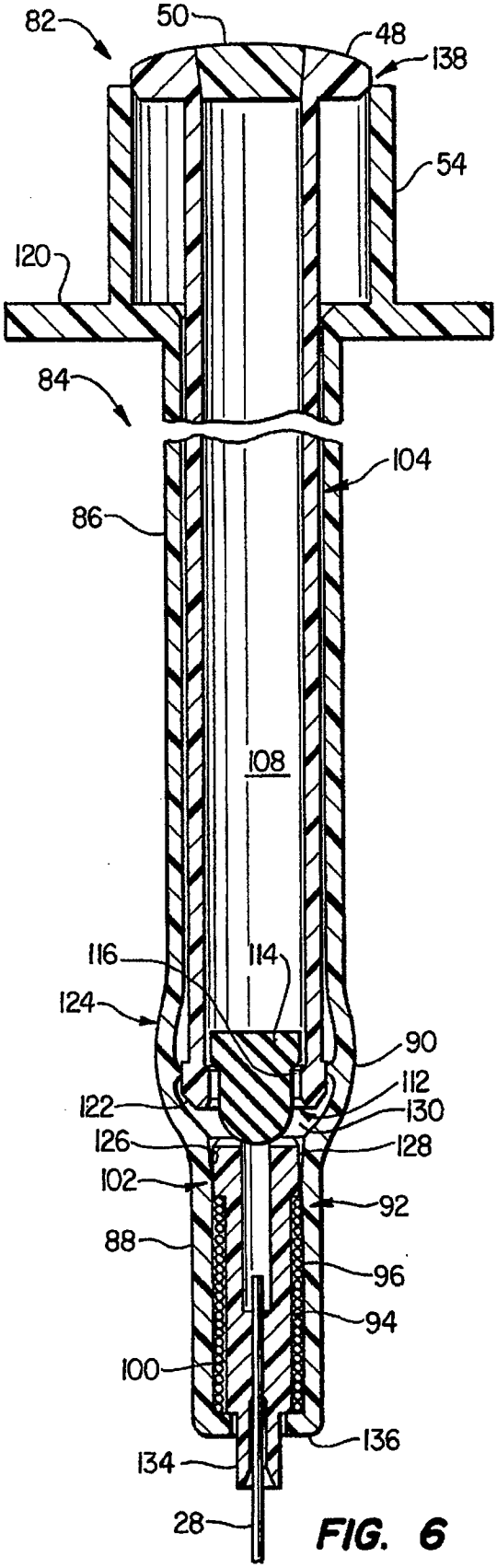
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FIG. 6

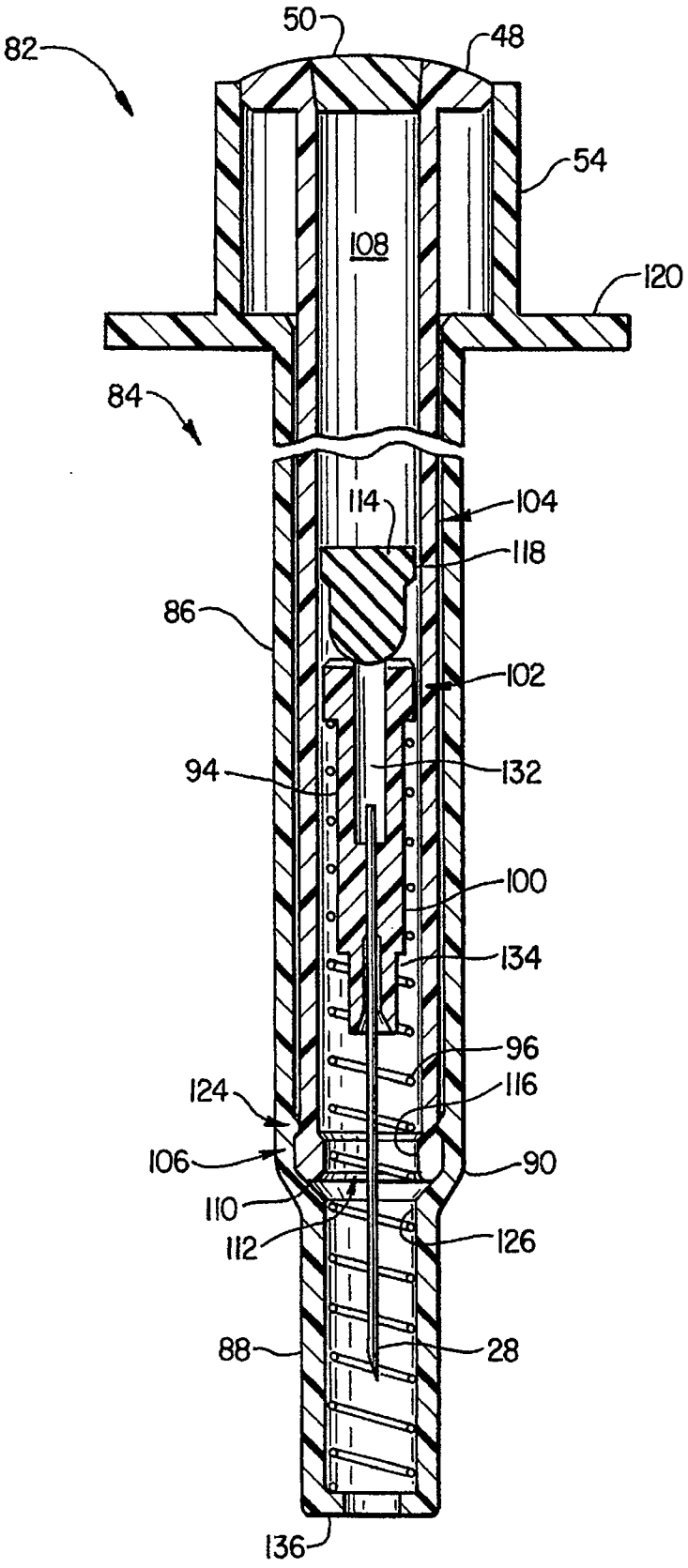
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FIG. 7

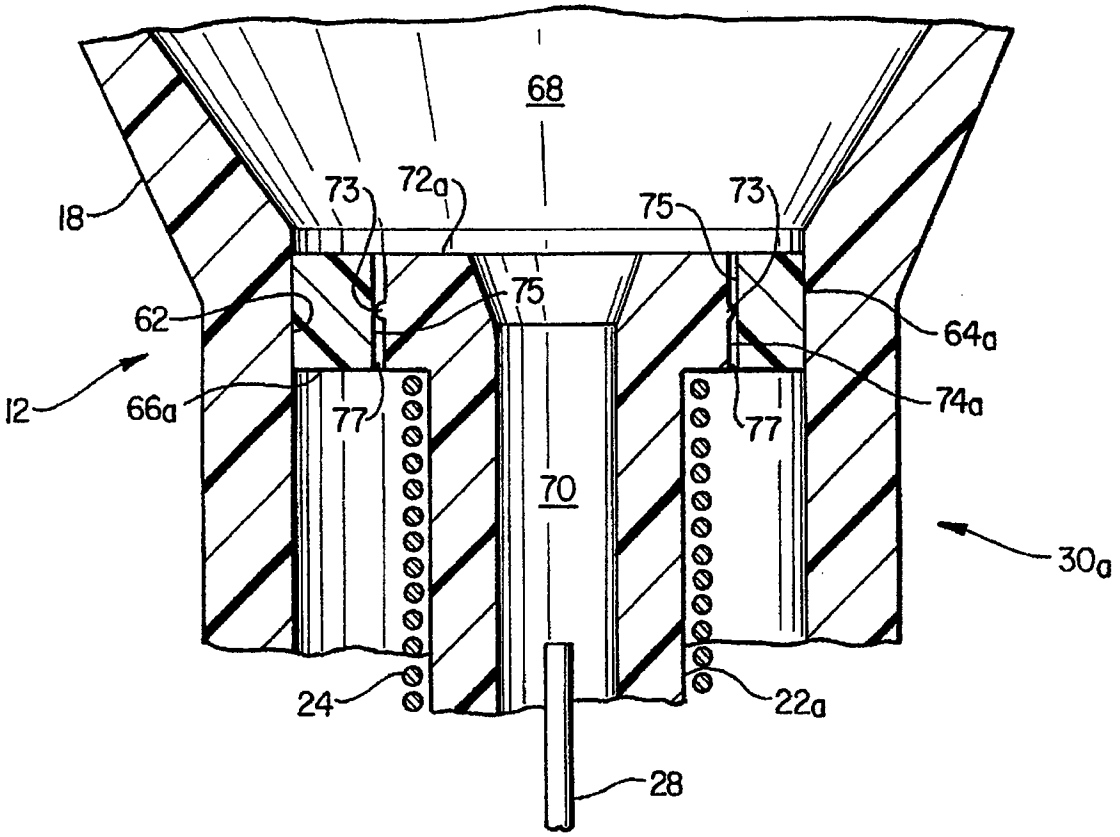

FIG. 8

TAMPERPROOF RETRACTABLE SYRINGE

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of copending patent application Ser. No. 08/438,954 filed May 11, 1995 by the same inventor entitled Tamperproof Retractable Syringe for which benefit is claimed under 35 U.S.C. §120.

FIELD OF THE INVENTION

This invention relates to a medical device, and more particularly to a retractable syringe suitable for mass production and assembly having a low triggering force and high blowout pressure which is nonreusable after one use.

BACKGROUND OF THE ART

A major cause to the spread of AIDS in the general population is the presence of IV drug users who share and reuse hypodermic syringes to inject drugs. Infection can be spread from AIDS patients in hospitals and medical facilities through accidental needle sticks from needles used on infected patients. Used syringes with extended needles present a risk to medical personnel and sanitation employees and others in the disposal chain.

The gravity of the threat posed by AIDS and the fact that the main vector of the spread of the dreaded disease is through reuse of syringes by IV drug users has resulted in intense activity to develop the most practical, most reliable, easily assemblable, mass-producible syringe.

There are a number of syringes of different designs which have needles which will retract at the end of the injection cycle. Most of these have never reached the market because of various deficiencies. Prime among the usual deficiencies of the prior art are problems of complexity, reliability, cost and ease of use. The most commonly used syringes are 1 cc and 3 cc syringes which must be mass-produced at the rate of millions per day. Cost is a significant factor both in manufacture of the parts and assembly of the device. High speed production requires molds with 64 cavities or more to reduce unit cycle time. Therefore, molded structures within the barrel that require collapsing core pins such as are shown in much of the art are unlikely to be producible at competitive costs.

One of the problems of the prior art of retractable syringes is the sheer number and complexity of parts which must be formed and assembled. Other problems with the prior art are dependence on flexing or breaking of internal parts by the plunger in order to release the retraction mechanism and use of a diaphragm at the end of the plunger which must be penetrated by a needle holding member and spring. These structures present serious quality control and assembly problems. Small broken off pieces can present a risk of hang-ups. Hooks are often used to releaseably secure retraction mechanisms. Hooks present difficult holding and control problems. may cause retention of air bubbles upon filling and may be undesirably temperature sensitive.

The prior art frequently has a two-piece barrel in order to be able to assemble a retraction device in the nose. This requires at least an additional part and assembly step. It is still necessary to pass the sharp injection needle through a small opening often while compressing a spring before the two parts can be assembled. The tiny needles are produced in the form of coil tubing and vary significantly from straightness after they are cut to length. This leads to difficult assembly problems if the needle must be passed through a small opening. The extremely sharp tip will catch the edge of a hole and jam the production line.

The rare prior art that employs a front mounted retraction mechanism in a one-piece barrel with a plugged hollow plunger, Tsao U.S. Pat. No. 5,084,018, among other things does not show reduced barrel area to prevent excessive blowout pressure, employs engaging flanges to secure all retraction parts, requires concurrent distortion of internal parts and flanges to effect release, cumulating in excessive force required to retract and requires ventilation holes because of a compartmented barrel.

The prior art has not produced a retractable nonreusable tamperproof syringe for mass production and assembly which is simple, reliable, cost effective, easy to use and retract, looks like a conventional syringe, has few parts which are easy to make and assemble, is not temperature sensitive and not subject to danger of premature retraction.

The prior art has not recognized a retraction mechanism with separable parts that relies entirely on clamping force or friction at a smooth walled reduced diameter transition zone in the barrel with mating lands which are slidably or separably released in response to relatively low thumb pressure while having resistance to premature retraction and high blowout pressure resulting from high pressure produced in the fluid chamber during an injection. The prior art has not recognized that such a structure can be molded as a one piece outer body over a core that can be pulled out from behind allowing the retraction mechanism to be easily pushed into place from behind, steered by the narrow nose portion. Neither does the prior art in such a combination realize the desirable non-cumulation of forces resisting retraction in order to minimize the thumb force required, having a most simple tamperproof feature and the fewest number of easily made parts. These features and more are found in the inventive combination herein further disclosed which is especially suited for high speed production and assembly at low cost.

SUMMARY OF THE INVENTION

The invention is a reliable retractable tamperproof syringe having multiple tamperproof features which operates on a principle which permits low cost parts which are few in number and well suited for high speed mass production and assembly. The syringe structure features a one piece hollow outer body having a longitudinally extending wall which is stepped. The wall comprises an elongated barrel and nose with a transition zone connecting the barrel and nose. The nose has a reduced diameter relative to the barrel. The outer body has an inwardly facing surface in the wall at the most constricted part of the transition zone where the nose begins. A plunger assembly is disposed partially within the elongated barrel with an end cap for depression of the plunger extending from an opening in the back of the barrel. The head of the plunger, which has a retraction cavity for receiving parts of a retraction mechanism, moves in slidable sealed contact with the interior of the barrel.

A retraction mechanism is lodged in the nose of the body. The retraction mechanism comprises an elongated needle holder and spring combination wherein the needle holder has an elongated body with a needle holding portion in front and a head in back. The head of the needle holder has a cooperating outwardly facing surface configured to cooperate with said inwardly facing surface along an interface oriented in the direction of retraction to produce a holding force on the needle holder when installed in the nose in the unretracted position. The needle holder and spring are easily

installable from the rear of the barrel toward the nose and releaseably held by sliding engagement of said cooperating inwardly and outwardly facing surfaces while compressing the spring and thereby producing a holding force on the needle holder in opposition to the retraction force applied to the needle holder by the spring. The parts are circular in cross section.

The outwardly facing surface on the circular head of the needle holder is slightly greater in diameter than the circular inward facing surface in the wall at the most constricted portion where the nose begins. The needle holder is thus clamped in position by hoop stresses induced in the outer body and held in position by frictional holding force. The needle holder is released in response to depression of the plunger to a retraction position. Retraction occurs in response to thumb force on the plunger when a portion of the plunger passing into the transition zone separates at least a portion of the inwardly and outwardly facing cooperating surfaces thereby reducing the holding force on the needle holder to an amount less than a retraction force on the needle holder produced by the spring whereby the needle holder is retracted into the cavity a distance sufficient to withdraw an injection needle, attached to the needle holder, into the outer body.

In one embodiment, the head of the needle holder is a two part head comprising an inner head surrounded by a separable retainer member wherein the outer surface of the retainer member is the outwardly facing surface with cooperates with the inwardly facing surface in the wall to retain the needle holder in an unretracted position at the most constricted part of the transition zone where the nose begins. The retainer member is a ring member coupled to the inner head along a sliding interface oriented in the direction of retraction with a friction force which exceeds the retraction force provided by the spring. The front of the needle holder is grounded in the nose portion against forward movement. The plunger head is configured to pass through the most constricted area and push against the retainer member without also pushing against the head of the needle holder. An alternate construction of the two part head of the needle holder comprises the separable retainer member being tack welded to the inner head of the needle holder, preferably along a very small ridge or bridge between the mating surfaces which holds the two part head together until the bridge is ruptured by movement of the plunger after an injection has occurred.

The front of the plunger has an opening for a stopper slidingly fitted therein in an interference fit. The stopper is fitted in the opening in an interference fit along a sliding interface oriented in the direction of retraction. The stopper is mostly or fully dislodged by contact with the retraction mechanism at the end of an injection cycle by continued depression of the plunger from a first position at the end of the injection cycle to a second position with the tip of the plunger in contact with the retainer ring. This avoids cumulation of the force on the plunger required to dislodge the stopper from the opening and the force required to dislodge the retainer member from the head of the needle holder and outer body wall. Upon further depression of the plunger from the second position to the retraction position, the frictional holding force on the needle holder is reduced until the retraction force provided by the spring exceeds the remaining holding force and the needle holder and needle connected thereto are ejected into the cavity carrying the dislodged stopper along with them. The dislodging of the stopper and the retainer member alone make the syringe non-reusable. The plunger cannot be removed after retraction because the graspable end cap enters an opening at the back of the barrel when the plunger is depressed to the retraction position to prevent tampering after retraction.

The syringe has a high blowout pressure and a low plunger thumb force required to cause retraction. Blowout pressure is the fluid pressure operating on the stopper and retainer ring during an actual injection. High blowout pressure resistance is obtained because the retainer ring is mounted in the most constricted potion of the barrel where the nose begins which significantly reduces the amount of area exposed to fluid pressure. The smaller retainer ring allows the use of a small needle holder such that the opening in the plunger and the stopper can be only a fraction of the cross sectional area of the fluid chamber below the plunger head. The ratio of the greatest cross sectional area of the variable chamber and that of the dislodgeable stopper or the ring member are selected so that the maximum expected thumb force on the plunger during an injection will produce a maximum pressure in the chamber which will generate a blowout force on the stopper and retainer member slightly less than the amount of dislodging force necessary to dislodge the stopper and retainer member during retraction. This ratio should be at least two to one, or more preferably three to one or more, in order to ensure against premature blowout of the stopper or retainer ring.

In an alternate embodiment, the fewest number of easily made separate parts are used in a retractable syringe. The alternate embodiment has a similar stopper in the head of the plunger and a similar needle holder and spring combination with mating cooperating inwardly facing and outwardly facing interengaged surfaces at the most constricted part of a transition zone where the nose begins. In the alternate embodiment, there is no retainer ring around the head of the needle holder. Instead a tiny ramp is provided at the transition zone or adjacent the transition zone whereby the head of the plunger gently spreads the barrel outwardly while dislodging the stopper thereby reducing the damping or friction force on the head of the needle holder provided by the wall of the outer body. The holding force is thereby reduced below the retraction force provided by the compressed spring and the needle holder is ejected into the cavity of the plunger carrying the dislodged stopper along with it.

Manufacture and assembly is facilitated by the fact that the plunger and the outer body can be molded with a non-collapsible core tool that can be pulled out from behind. The parts are simply shaped and do not have hooks and parts with reentrant angles that require collapsible core pin technology. The outer body can be made in one piece and assembled from the rear. The narrowed nose portion provides no lateral space with will permit bunching of the spring and jamming when the retraction assembly is moved forward in the outer body. In fact, the nose serves as a guide to steer the parts into the proper position in one smooth stroke.

The needle does not have to be installed before the retraction mechanism is put in place because it is readily installed from the front after the needle holder is slidingly lodged in the nose. Significant variations in the holding force on the needle holder and the dislodging force on the stopper due to slight variances in the tolerance of the mating parts is avoided because the longitudinal wall of the outer body has some flexibility. The wall can spread outwardly slightly and the stopper and head of the needle holder can compress slightly radially and expand slightly in the longitudinal direction to avoid significant changes in the holding force caused by small changes in the actual diameters. Consis-

tency in the amount of retraction force is thereby provided and economy is assured.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross section along the central axis of a first embodiment of the invention with the plunger positioned in a first position at the end of an injection cycle;

FIG. **2** is the syringe of FIG. **1** with the plunger depressed additionally to dislodge the stopper at a second position of the plunger wherein the tip of the plunger is ready to operate the retraction mechanism;

FIG. **3** is the syringe of FIG. **2** wherein the plunger has been further depressed to a retraction position, retraction has occurred and the cap at the back of the plunger is closely received in an opening at the back of the outer body;

FIG. **4A** is a partial cross section on the central axis of an alternate tamperproof opening in the back of the outer body prior to retraction;

FIG. **4B** is the structure of FIG. **4A** with the plunger in the retracted position received in an opening at the back of the outer body;

FIG. **5** is a cross section along the central axis of a simplified alternate syringe structure without a retainer member around the needle holder, which is released by separation of the friction surfaces, shown in the plunger position which represents the end of an injection cycle;

FIG. **6** is the syringe structure of FIG. **5** wherein the plunger is further depressed to dislodge the stopper and begin to release the friction surfaces just prior to retraction;

FIG. **7** is the syringe structure of FIG. **6** with the plunger further depressed beyond the position of FIG. **6** to the retraction position where retraction has occurred and the cap is secure within an opening in the back of the hollow outer body.

FIG. **8** is a schematic longitudinal cutaway view in elevation through the center of the two part head showing how a tack weld can be applied to simultaneously seal and hold the retainer ring in place on the needle holder.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the description that follows, like parts will be referred to by the same reference numerals. Parts with a sub script letter are mean to illustrate a minor variation of a part with the same number. The drawings are enlarged significantly in order to show the details of the invention but generally reflect the true scale which is contemplated. The parts as shown are understood to be preferably circular and symmetrical as is conventional for syringes. The drawings reflect a syringe structure having a 1 cc to 3 cc injection fluid capacity.

FIG. **1** shows the structure of the first embodiment generally referred to by reference numeral **10**. Syringe **10** has a one piece hollow outer body **12**. Body **12** has a longitudinally extending wall comprising an elongated barrel **14** and a nose **16** with a transition zone **18** connecting the barrel and nose. A front mounted retraction mechanism lodged in the nose is generally referred to by the reference numeral **20**. It comprises the combination of an elongated needle holder **22** and spring **24**. The needle holder has an elongated body with a needle holding portion **26** in front for holding a needle **28** and a head **30** in back. Head **30** may consist of a two part head as in FIGS. **1–3** or a one part head as in FIGS. **5–7**. The needle holder is released by depression of a plunger that will be described.

A plunger generally designated by the reference numeral **32** is disposed for use partially within barrel **14**. The plunger has a head and seal generally referred to by reference numeral **34**, in slidable sealed contact with the interior of barrel **14** of outer body **12**. The plunger has a seal element **36** that is conventional and a retraction cavity **38** therein.

Head **34** has a tip portion **40** forming an opening **41** into retraction cavity **38**. A resilient dislodgable stopper **42** is sealingly positioned in opening **41** with a front portion thereof extending beyond tip **40**. Head portion **34** and the back part of stopper **42** have cooperating lands **44**, **46**, respectively, which seal opening **41**. Plunger **32** has an end cap **48** for depression of the plunger by the thumb. End cap **48** has a central opening for permanently receiving force fit plug **50** to close retraction cavity **38** at the back end.

A plurality of longitudinally extending flutes **52** slidingly support plunger **32** in barrel **14**. In the embodiment of FIG. **1**, outer body **12** has a collar **54** extending behind finger grips **56** having opening **58** which closely receives the outer periphery **60** of cap **48** when the plunger is depressed to the retracted position. An alternate arrangement is shown in FIGS. **4A** and **4B** in which barrel **14** is extended longitudinally, if necessary, so that end cap **48** fits closely within an opening at the back of the barrel where the finger grips are. FIG. **4B** shows the tamperproof position with the plunger in the retracted position. It should be noted that depending on the relationship of the inside diameter of the barrel and the diameter of the end cap, the end cap could instead be received right inside the opening at the back of the barrel. Regardless of how the end cap in back of the outer body and barrel are configured, the plunger can no longer be grasped after retraction has occurred because end cap **48** is depressed into an opening.

The wall of outer body **12** and head **30** of the needle holder have mating cooperating smooth surfaces which hold needle holder **22** in the position shown in FIG. **1** with spring **24** compressed. Nose **16** has a reduced diameter relative to the barrel. The outer body has a most constricted part where head **30** of needle holder **22** is engaged and held. The outer body has an inwardly facing surface **62** at the most constricted part of the transition zone where nose **16** begins. Similarly, head **30** has an outwardly facing surface **64** configured to cooperate with inwardly facing surface **62** to produce a holding force on needle holder **22** when the retraction mechanism is installed in the nose from the rear. Mating surfaces **62**, **64** constitute a sliding interface oriented in the direction of retraction, which seals nose **16**. Mating surfaces **62**, **64** are preferably friction surfaces which have an interference sliding fit to apply a frictional holding force which holds needle holder **22** in position by friction between the mating parts. It is within contemplation of the invention that one or more of the cooperating interface surfaces could employ a coating or adhesive bond which is ruptured or released when the mating surfaces or lands are separated or moved relative to each other.

Head **30** provides a lower boundary for a variable fluid chamber **68** below head **34**. Needle holder **22** has a fluid path **70** in fluid communication with fluid chamber **68** and needle **28**. Needle holder **22** has a smaller diameter inner head **72** which is part of head **30**. Retainer member **66** is coupled to inner head **72** along sliding interface **74** oriented in the direction of retraction. Retainer member **66** is coupled to inner head **72** with a holding force which exceeds a retraction force applied to the underside of inner head **72** by means of the end of compressed spring **24**. A reduced diameter portion **27** of needle holder **22** protrudes through an opening in front **76** of nose **16**.

Importantly, retainer member **66** can be visualized as an annular ring surrounding circular inner head **72**. The location of retainer member **66** at the most constricted part of the transition zone where the nose begins and the relatively small area exposed to pressurized fluid in chamber **68** results in a high blowout pressure. Since the front portion **26** of the needle holder is grounded or bottomed inside front **76** of nose **16**, no amount of pressure will allow needle holder **22** or needle **28** to move forward. Blowout pressure may be defined as the pressure in chamber **68** acting on the exposed area of retainer member **66** to produce a force sufficient to overcome the holding force such that retainer **66** could "blowout" by moving forward and prematurely release needle holder **22**.

Some users have strong hands and might, at the outer limit in an emergency, be able to generate a force of as much as fifteen to eighteen pounds on the plunger during an injection. It is considered almost impossible for anyone to exert a force of more than eighteen pounds. This may be regarded as the maximum expected force which must be taken into account so that ring member **66** will not blowout while an injection is being made. The greatest cross sectional area of variable chamber **68** and the area of retainer member **66** exposed to fluid pressure are selected so that the blowout pressure is higher than the maximum pressure in chamber **68** expected to result from the maximum expected thumb force applied to cap **48** during an injection. This milo is preferably about two to one and more preferably about three to one or more so that the holding force holding the retraction mechanism in place can be kept at a comfortably low level while the blowout pressure remains high.

Dislodgeable stopper **42** has a similar blowout problem to recognize. The front and middle portion of stopper **42** are relieved slightly from opening **41** such that the fluid pressure in chamber **68** is directed against the cross sectional area at cooperating lands **44**, **46** and could cause stopper **42** to blowout. A frictional holding force is generated at the lands **44**, **46** which may be called a dislodging force which must be overcome to slide stopper **42** rearwardly before retraction. The ratio of the maximum cross sectional area across the interior of variable chamber **68** to the maximum cross sectional area of stopper **42** exposed to pressure in chamber **68** are selected so that the maximum expected thumb force on plunger **32** during an injection will produce a maximum force slightly less than the amount of dislodging force necessary to dislodge the stopper so that stopper **42** will not blowout during an injection. This ratio is preferably not less than about two to one, more preferably three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds, respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The stopper is dislodged after the injection by thumb force applied to the stopper by movement of the plunger.

The components used for retraction are arranged to avoid cumulation of force during the retraction sequence. In FIG. **1**, stopper **42** has a forward extension beyond tip **40** which allows full thumb pressure to be applied to the stopper before any other portion of the retraction mechanism is engaged. The amount of forward extension beyond tip **40** is related to the length of lands **44**, **46** such that the forward extension of stopper **42** preferably represents about 80 percent of the engaged land length. When stopper **42** is moved back until the front is even with tip **40**, as seen in FIG. **2**, only about **20** percent of engaged land remains. In FIG. **2** it can be seen that thumb force on plunger cap **48** has been applied to partially dislodge stopper **42** such that a gap **78** is created and the remaining engaged land area is represented as area **80**.

Since I believe the amount of frictional holding force or dislodging force is roughly proportional to the amount of the length of the sliding interface between cooperating lands **44**, **46**, it follows, ignoring dynamic effects, that the amount of force remaining decreases as the engaged sliding interface area is reduced. This is what happens as stopper **42** moves back into cavity **38** from the position of FIG. **1** to the position of FIG. **2**. It is believed appropriate to set the initial dislodging force to allow about five pounds at the position of FIG. **1** which is reduced to about one pound remaining when the stopper or plug member **42** reaches the position of FIG. **2**. It might be noted at this point in the description that the front portion of tip **40** preferably has some longitudinally extending slits or openings so that fluid is not trapped in the trapezoidal shaped area of chamber **68**, seen in FIG. **2**, because of contact between tip **40** and the upper surface of retainer ring **66**.

Needle holder **22** and spring **24** are combinably installable from the rear of the barrel before the plunger is assembled and releasably held at the most constricted part of the transition zone where the nose begins by sliding engagement of the cooperating inwardly and outwardly facing friction surfaces **62**, **64** while compressing spring **24**. The length of the engaging land **64** and the amount of interference fit is preferably designed to provide a frictional holding force in opposition to the retraction force provided by the compressed spring **24** of somewhere around five pounds even though the spring may apply a retraction force in the retraction direction of somewhere around a half pound. In use the needle is pushed against a rubber seal in a vial so the needle holder must resist a resulting backward force without being dislodged during the filling operation. This requirement and blowout pressure limits the low end of the holding force on the needle holder.

Referring again to FIG. **2**, it can be seen that further depression of the plunger beyond the second position of FIG. **2** dislodges retainer ring member **66** along the sliding interface **74** provided by the outer surface of inner head **72** and along the inwardly facing friction surface **62**. As the amount of remaining engaged interface is reduced, the amount of force required to continue moving retainer member **66** off needle holder **22** is reduced and the small remaining engagement area **80** between lands **44**, **46** of the plunger and stopper preferably cause stopper **42** to be dislodged before needle holder **22** is released. When the remaining residual friction force during continued depression of the plunger becomes less than the retraction force provided by compressed spring **24**, the retraction position of FIG. **3** is reached whereby retraction occurs.

When retraction occurs needle holder **22** moves through opening **41** into cavity **38**. The uncompressed length of spring **24** is selected to provide backward movement sufficient to withdraw an injection needle **28** fixed in front portion **26** entirely within outer body **12**, carrying dislodged stopper **42** with it. At the same time, cap **48** enters opening **58** of the barrel with peripheral edge **60** closely confined, in order to prevent tampering after retraction. It is immaterial whether cap **48** moves into the opening at the instant of retraction or after retraction has already occurred because the movement is automatic due to the continued thumb force applied to trigger the retraction. Sufficient unengaged length of inwardly facing friction surface **62** is provided so that retainer member **66** can move downwardly a sufficient

distance to reach the retraction position of FIG. **3**. After retraction, retainer member **66** preferably remains stuck and prevents any possibility of any one being able to reengage it with the head of needle holder **22**. The diameter of land **62** in the area designated **63** can be increased slightly to provide relief for retainer ring **66** as it is pushed down by tip **40**.

It is also within the contemplation of the invention that separable retainer member **66** may be removably coupled to inner head **72** of needle holder **22** by means of a relatively small in area "tack" weld which is sufficient to resist the retraction force applied to needle holder by spring **24** but which can be ruptured or separated by depression of the plunger beyond the position shown in FIG. **2**, to release the needle holder and allow retraction. This is schematically illustrated in FIG. **8** with respect to alternate head **30***a* with the parts of syringe body **12** and needle holder **22** cutaway to focus on the modification. The remainder of the syringe structure would be like FIGS. **1–3**.

In FIG. **8**, inner head **72***a* has an outwardly facing surface **74***a* and a very small raised portion or series of horizontally spaced apart raised potions **73** around the periphery in a continuous band or annular ring which extend relatively uniformly outwardly beyond peripheral surface **74***a* of head **72***a*. The raised portion could be on the inner surface **75** of retainer **66***a* instead of being on surface **74***a* of the needle holder. The head of the needle holder is preferably circular but could be conceivably another shape with the retainer member **66***a* correspondingly configured to conform to it.

The inwardly facing surface **75** of inner head **72***a* is in contact with raised portion **73** on the outer surface of inner head **72***a* and there may be a small gap **77** between them all around. The raised potion **73** couples retainer **66***a* to inner head **72***a* and may be referred to as a bridging portion which resists the blowout pressure referred to above and holds the needle holder in place against the retraction force imposed on the needle holder by spring **24** together with any small additional forces that may be applied when the needle is pushed against the rubber seal of a vial in preparation for use. The bridging portion may be formed by "tack" welding the raised portion **73** to the inner surface of the ring **66***a* or by providing any other form of frangible bridging portion that holds the separable ring member **66** and needle holder head **72***a* together. It is required that however done, the bridging portion must also serve as a seal between the facing surfaces of the ring member and inner head so that fluid under pressure cannot pass from chamber **68** through gap **77** to reach the nose portion of the device. All fluid must pass through fluid passage **70**.

It can be seen that when the position of FIG. **2** is reached the front tip **40** of the plunger presses against retainer ring **66***a* after stopper **42** is almost dislodged and uncouples the retainer ring **66***a* from the inner head **72***a* of needle holder **22***a*. Any tack weld connecting the separable parts at the bridging portion is ruptured, fractured or otherwise separated so as to separate retainer ring **66** a from inner head **72***a* thus releasing needle holder **22***a* from further restraint. They and the force applied by spring **24** causes retraction to occur much as before described and shown in FIG. **3**.

It is believed that the increased diameter of the raised portion **73** should be within the range of about 1 to 8 thousandths of an inch which may be dictated by the ability of the molding equipment available to produce a consistent bridging portion without defects. It is believed that it may be desirable to employ different polymeric materials for the retainer ring and needle holder to facilitate tack welding, such as a suitable polyvinyl chloride (PVC) for the retainer ring and a suitable polycarbonate plastic material for the needle holder. One way to couple these two parts may be to assemble them and expose them to a temperature of about 120° C. for twenty minutes or so to allow some diffusion or incipient melting to occur where they touch. The raised potion creates a high unit pressure where it comes into contact with the inwardly facing surface of retainer **66***a*. Sonic welding could also be employed. A coating or adhesive which couples the retainer ring to the needle holder and can be uncoupled by means of force applied to the retainer ring by the plunger is also within the contemplation of the invention.

An alternate syringe **82** is disclosed in FIGS. **5–7**. In FIG. **5**, Syringe **82** has a one piece hollow outer syringe body **84**. Body **84** has a longitudinally extending wall comprising an elongated barrel **86** and a nose **88** with a transition zone **90** connecting the barrel and nose. A front mounted retraction mechanism lodged in nose **88** is generally referred to by the reference numeral **92**. It comprises the combination of an elongated needle holder **94** and spring **96**. The needle holder has an elongated stem body with a needle holding portion **100** in front for holding needle **28** and a head **102** in back. In this ease, head **102** is a one part head integral with the rest of needle holder **94**. Spring **96** delivers a retraction force in a retraction direction to the underside of head **102**.

A plunger generally designated by reference numeral **104** is disposed for use partially within barrel **86**. Plunger **104** has a head portion **106** which moves in slidable sealed contact with the interior of barrel **86** of outer body **84**. Although a separate seal might be used on head **106**, this embodiment is suitable for a smaller diameter, such as a Ice syringe, and can be used with head **106** also serving as the seal. A retraction cavity **108** is provided in the interior of hollow plunger **104**. Head **106** has a tip portion **110** forming an opening **112** for a dislodgable stopper **114** having a front portion extending beyond tip **110**. Head portion **106** has an inwardly facing land **116** and the back of stopper **114** has an outwardly facing land **118** comprising cooperating friction surfaces which seal opening **112**. The back portion of outer body **84** may have finger grips **120** and the same collar **54** and end cap **48** previously disclosed. The alternate arrangement of FIGS. **4A** and **4B** may also be employed.

The outer portion of tip **110** may be equipped with an angled surface **122** designed to cooperate with a small ramp surface **124** located in the vicinity of transition zone **90**. The wall of outer body **84** and head **102** of the needle holder have mating cooperating friction surfaces which frictionally hold needle holder **102** in the position shown in FIG. **5** with spring **96** compressed. Nose **88** has a reduced diameter relative to barrel **86**. The outer body has a most constricted part where the head **102** of needle holder **94** is frictionally engaged. The outer body has an inwardly facing surface or land **126** at the most constricted part of the transition zone where nose **88** begins. Similarly, head **102** has an outwardly facing friction surface **128** configured to cooperate with inwardly facing surface **126** to produce a frictional holding force on needle holder **94** when the retraction mechanism is installed in the nose from the rear.

Mating surfaces **126**, **128** constitute a sliding interface oriented in the direction of retraction, which seal nose **88**. Mating surfaces **126**, **128** are preferably smooth friction surfaces which have an interference sliding fit when needle holder **94** is installed from the rear whereby a frictional holding force holds needle holder **94** in position by friction between land **126** and head **102** of needle holder **94**. It is within contemplation of the invention that one or both of these surfaces could have a coating or adhesive bond which is ruptured when the mating surfaces are separated to release the needle holder.

Head **106** provides the upper boundary for a variable fluid chamber **130** below head **106**. Needle holder **94** has a fluid path **132** in fluid communication with chamber **130** and needle **28**. Needle holder **94** is releasably coupled at surfaces or lands **126**, **128** with a holding force that exceed the

retraction force applied to the underside of head **102** by the end of compressed spring **96**. A reduced diameter portion **134** of needle holder **94** protrudes through an opening in front **136** of nose **88**. Blowout pressure is not a factor with respect to the needle holder on the alternate embodiment. No amount of pressure will allow needle holder **94** or needle **28** to move forward since the front portion **100** of the needle holder is grounded or bottomed inside front **136** of nose **88**.

Blowout pressure is still a factor to be considered in connection with stopper **114**. Blowout pressure would be the pressure in chamber **130** produced by thumb force on cap **48** acting on the cross sectional area of stopper **114** which could overcome the holding force, causing stopper **114** to dislodge from opening **112** prematurely. The ratio of the maximum cross sectional area across the interior of variable chamber **130** to the maximum cross sectional area of stopper **142** exposed to pressure in chamber **130**, and the dislodging force necessary to dislodge stopper **144**, are selected so that the maximum expected thumb force on plunger **104** during an injection will not cause the stopper to blowout. Yet the stopper will still be dislodged by the dislodging force on the plunger once the front of stopper **114** contacts the retraction mechanism after the injection has ended. The ratio referred to is preferably not less than about two to one, or more preferably about three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The smaller diameter stopper allows two or three times the thumb force to be used during the injection cycle than required to actually dislodge the stopper by direct application of force.

By reference to FIGS. **5–7**, the operation and further features of the alternate embodiment are discussed. The syringe is used in the normal manner until the plunger is depressed to the first position of FIG. **5** which is the end of the injection cycle. Stopper **114** has a forwardly extending end which has come into contact with head **102** of needle holder **94** to block fluid path **132**. Further depression of plunger **104** toward the position of FIG. **6** mostly or fully dislodges stopper **114** and begins spreading barrel **84** at the transition zone by sliding contact between head potion **106** and ramp **124**. Ramp **124** is a very small inwardly extending annular thickening of the wall of barrel **86** which can take many shapes or forms. For example, ramp **124** may be a small step **125** in the wall which continues vertically downward as indicated by the dotted fine, which is somewhat exaggerated in FIG. **5**.

The barrel is flexible and is spread outwardly a slight amount to the position of FIG. **6** just prior to retraction. Here the mating surfaces **126**, **128** are separated an amount which reduces the clamping force on the needle holder **94**. The spreading shown in FIG. **6** is greatly exaggerated for illustration. It is estimated that an expansion of only about four thousandths of an inch is sufficient to release needle holder **94** from nose **88**. By slight further depression of the plunger from the position of FIG. **6** to the retracted position of FIG. **7**, retraction occurs when the retraction force applied by spring **96** exceeds the remaining holding force on needle holder **94**. Needle holder **94** then moves through opening **112** into cavity **108** along with a portion of spring **96**. The uncompressed length of spring **96** is designed to provide sufficient backward movement to withdraw an injection needle **28** fixed in front portion **94** and carry dislodged stopper **114** with it. At the same time, cap **42** enters opening **138** at the rear of a barrel extension **54** where the peripheral edge is closely confined in order to prevent tampering after retraction.

The location and configuration of ramp **124** is arranged to avoid cumulation of force required during the retraction sequence. Most of stopper **114** should be dislodged by thumb pressure on plunger **104** before significant resistance develops as angled surfaces **122** begin pushing outwardly on ramp **124**. The selection of the location of ramp **24** and the angle of the engaging surfaces make it possible to have a fairly smooth continuous force since the dislodging force continuously decreases as the sliding interface area **116**, **118** between the plunger and the stopper is linearly decreased. Because ramp **124** is relatively very small, it is still possible to remove a stepped molding core from the rear of the outer body **84**. Alternately, ramp **124** can be the smaller diameter step **125** which avoids reentrant angles whereby resistance to removal of the molding core could occur. After retraction, the back of the plunger is unaccessible and there is no way to reach to stopper or the needle holder in order to reinstall them for re-use.

In operation, there are many advantages to the improved combination disclosed herein. The diameter of the stopper in both embodiments and the slidable retaining ring member in the first embodiment, in relation to the diameter across the fluid chamber, makes it possible to produce a syringe which withstands high blowout pressure. By minimizing the effective surface area exposed to the pressurized fluid during an injection, the syringe will withstand injection thumb force of around fifteen to eighteen pounds during injection and at the same time retract in response to as little as five to six pounds of force on the plunger once the injection fluid has been injected. Once the fluid has been injected, cumulation of force required to concurrently operate the retraction mechanism is avoided. First the stopper is moved back and then the needle holder is released. By constricting the diameter of the syringe near a transition zone where the nose begins, a constriction enables the needle holder to be smaller which in turn allows it to fit in a smaller opening with a smaller stopper in the retraction cavity of the hollow plunger.

A vacuum must be pulled in order to fill the syringe. The ring member or the needle holder, as the case may be, must seal the front nose of the syringe body because otherwise vacuum could be lost and fluid could enter the spring area and leak out the front. The hollow outer body and syringe plunger are preferably made from conventional plastic material used for syringes, which has some flexibility. The tolerances on the diameter of mating facing surfaces between the head of the needle holder and the barrel and between the stopper and head of the plunger are not critical in order to maintain a consistent holding and dislodging force. This is believed to be because increasing interference fit increases the frictional holding force only up to a point and then the surrounding wall simply expands a small amount or the internal parts are compressed a small amount without a corresponding increase in the longitudinal force required to move the retainer member or plug member in the retraction direction. It is a desirable self correcting mechanism which is a cost and quality benefit in making the parts. It is believed that a plastic retainer member could be used and the same self limiting fictional holding force would be obtained.

In the best mode the stopper and the ring member are preferably made from a thermoplastic rubber material designated number 181-55 available from Advanced Elastomer Systems, 540 Maryville Centra Drive, St. Louis, Mo. and sold under the trade name Santoprene®. It is said to have a characteristic hardness around 55 on the Shore A durometer scale which allows for the right amount of resistance to compression, fluid resistance such that the material does not swell when in contact with most fluids, environmental stability allowing the friction and sealing properties to remain non-temperature sensitive, good property retention

after aging and excellent property retention after sterilization by all accepted methods. The plunger seal around the head of the plunger is conventional.

The parts are few in number and easily mass produced. The alternate embodiment has the fewest number of separate parts of any tamperproof retractable syringe. The plunger has a one piece hollow outer body with a transition zone and a narrow nose portion. The internal diameter is stepped to greater diameters from front to back for molding around a non-collapsible core which can be extracted from the rear. The same is true for the plunger.

Assembly is greatly simplified and can be accomplished with high speed mechanized equipment. The needle holder and spring are installable from the rear of the barrel without the needle. In the first embodiment the retainer member is forced fit over the inner head of the needle holder and the assembly together with the uncompressed spring are pushed forward and held by sliding engagement of the cooperating inwardly and outwardly facing surfaces while compressing the spring. The front of the needle holder passes through an opening in the nose which makes it easy to install the needle from the front by conventional means. The alternate embodiment is installed the same way except that there is no separable retainer member around the head of the needle holder.

The narrow nose provides a particular advantage for mechanized assembly. The nose has a wall defining an elongated internal cavity which closely confines the spring and needle holder combination. During installation this cavity serves as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring. This solves an important assembly problem. If there is much lateral space in the nose around the spring, when the uncompressed spring is being compressed, it is a laterally unstable column which flexes sideways and bunches up causing a jam up. It might be added that rounded edges on the bottom of the slot directly below retainer **66** would further facilitate entry of the end of the spring.

The stopper is also installable from the rear of the plunger by pushing it forward until the cooperating lands are slidingly engaged. Then plug member **50** is force fit or otherwise fixed in the opening at the back of the plunger and the plunger is installed in the outer body. It is not necessary to try to pass the sharp needle through an elongated body with constricted openings where slight misalignment could cause hangups. The head of the needle holder simultaneously acts as a seal as well as a holding device such that no seal is required at the tip of the nose and no ultrasonic welding of separate parts is required.

There is no necessity for using internal locking teeth of any kind. No locking teeth are needed to hold the retraction mechanism or to lock the plunger after retraction. Locking teeth present difficult molding and quality control problems, tend to be temperature sensitive and tend to require a larger diameter barrel which increases premature blowout problems. In addition to the non-reusability provided by separation of the retainer ring from the head of the needle holder and dislodgement of the stopper, the plunger is not accessible after retraction because it is depressed within an opening at the back of the outer body. This additional tamperproof feature is provided in a one piece body without the necessity for hooking anything or twisting anything. The easily made and installed force fit plug at the back of the retraction cavity prevents access to the retracted components. The Federal government has fights in the invention under 35 U.S.C. §203. The Federal government has a nonexclusive, nontransferable irrevocable, paid up license to the invention.

I claim:

1. A tamperproof retractable syringe for injecting fluid wherein the syringe has a one piece body and a retraction mechanism assembleable from the rear which resists high blowout pressure during an injection but can be retracted with low plunger force after an injection, comprising:

a one piece hollow outer body having a longitudinally extending wall, comprising an elongated barrel and nose, with a transition zone connecting the barrel and nose, the nose having a reduced cross sectional area relative to the barrel and an inwardly facing surface in the wall at the most constricted part of the transition zone where the nose begins;

a plunger assembly disposed partially within the elongated barrel, the plunger having a head in slidable sealed contact with the interior of the outer body, a forward portion and a retraction cavity therein for receiving parts of a retraction mechanism;

a retraction mechanism sealingly disposed in the nose, the retraction mechanism having a retractable part comprising a needle holder having an elongated body having a needle holding tip portion in front and a head in back, a passageway defining a fluid path into a variable fluid chamber in the barrel below the plunger, and a spring applying retraction force to the retractable part, said retractable part being configured to be able to retract into the retraction cavity of the plunger when retraction is initiated;

the retraction mechanism further including a nonretractable part comprising a retainer member surrounding the head of the needle holder, the retainer member and said head of the needle holder being removably coupled by a bridging portion between them;

the needle holder and spring being installable into the nose from the rear of the barrel and releaseably installed by sliding engagement of said retainer member and said inwardly facing surface while compressing said spring, said sliding engagement producing a holding force in opposition to the retraction force applied to the needle holder by said spring; and

the plunger being depressible to a first position which comprises the end of an injection cycle whereby fluid previously drawn into the variable chamber is expelled through said fluid path, and a retraction position beyond said first position wherein retraction is initiated by the forward portion of the plunger head moving through the transition zone in the nose to release the needle holder by uncoupling the retainer member and needle holder at said bridging portion thereby reducing the holding force to an amount less than the retraction force on the needle holder to cause retraction of the retractable part into the retraction cavity of the plunger.

2. The tamperproof retractable syringe of claim **1** wherein said bridging portion constitutes a raised portion on one of the retainer member or the needle holder comprising a tack weld which is separated to uncouple the retainer member from the needle holder.

3. The tamperproof retractable syringe of claim **1** wherein the head of the needle holder and retainer member at the most constricted part of the transition zone where the nose begins comprise a lower boundary for the variable fluid chamber below the plunger head.

4. The tamperproof retractable syringe of claim **3** wherein the ratio of the greatest cross sectional area of the variable chamber to the area of the retainer member exposed to pressurized fluid in the variable chamber at the lower boundary during an injection is selected so that the retainer member has a high blow out pressure higher than the maximum expected pressure resulting from the maximum expected thumb force on the plunger so that the retainer member will not blowout prematurely during an injection.

5. The tamperproof retractable syringe of claim 4 wherein the ratio of the greatest cross sectional area of the variable chamber to the cross sectional area of the retainer member exposed to fluid in the variable chamber at the lower boundary is not less than about two to one so that high fluid pressure can be resisted while retaining a relatively low force on the plunger necessary to cause retraction.

6. The tamperproof retractable syringe of claim 5 wherein said ratio is not less than about three to one for improved resistance to high blowout pressure.

7. The tamperproof retractable syringe of claim 1 wherein the forward portion of the plunger head has an opening therein leading to the retraction cavity, said opening being sealingly closed by a dislodgeable stopper which slides relative to the plunger in response to dislodging force applied to the stopper by depression of the plunger at the end of the injection cycle before the initiation of retraction occurs.

8. The tamperproof retractable syringe of claim 7 wherein the dislodgeable stopper has an extended forward end which contacts the needle holder at the end of an injection whereby said dislodging force is applied during continued depression of the plunger prior to the initiation of retraction.

9. The tamperproof retractable syringe of claim 7 wherein the ratio of the greatest cross sectional areas of the variable chamber and the dislodgeable stopper is selected so that the maximum expected thumb force on the plunger during an injection will produce a maximum pressure in the chamber fluid which will generate a force on the stopper less than the amount of dislodging force necessary to dislodge the stopper so that the stopper will not blowout prematurely during an injection.

10. The tamperproof retractable syringe of claim 9 wherein said ratio of the cross sectional area of the variable chamber to the cross sectional area of the dislodgeable stopper is at least about two to one so that at least twice the force necessary to dislodge the stopper can be applied to the plunger during an injection without blowout of the stopper.

11. The tamperproof retractable syringe of claim 10 wherein said ratio is at least about three to one.

12. The tamperproof retractable syringe of claim 3 wherein the forward portion of the plunger head has an opening therein leading to the retraction cavity, said opening being sealingly closed by a dislodgeable stopper which slides relative to the plunger in response to dislodging force applied to the stopper by depression of the plunger at the end of the injection cycle before the initiation of retraction occurs.

13. The tamperproof retractable syringe of claim 12 wherein the ratio of the greatest cross sectional area of the variable chamber to the area of the retainer member and to the area of the stopper exposed to pressurized fluid in the variable chamber during an injection are selected so that the maximum expected thumb force on the plunger during an injection will produce a pressure force on the stopper and retainer member slightly less than the amount necessary to dislodge them so that they will not blowout during an injection.

14. The tamperproof retractable syringe of claim 13 wherein said ratios are not less than about two to one.

15. The tamperproof retractable syringe of claim 14 wherein one of said ratios is not less than about three to one.

16. The tamperproof retractable syringe of claim 1 wherein the plunger has a graspable end cap for depressing the plunger and a length selected to allow the end cap to enter an opening of the barrel when the plunger is depressed to cause retraction in order to prevent tampering.

17. A method of assembling a tamperproof retractable syringe which is well suited for automated assembly;

providing a one piece hollow syringe body having a longitudinally extending wall with an open back end, comprising an elongated barrel and nose portion of reduced cross sectional area relative to the barrel, and an inwardly facing surface in the wall at the most constricted part of a transition zone between the barrel and nose where the nose begins;

providing a needle holder having a fluid path, the needle holder having an elongated body portion in front and a head end in back, and providing a spring under the head end which circumscribes the needle holder;

providing a retainer member having an opening surrounded by a wall wherein the wall has an inner surface which defines the opening, said opening being sized to receive and releasably couple the head of the needle holder with a holding force which exceeds a retraction force applied to the needle holder by the spring, said retainer member having an outwardly facing surface sized to slidingly and frictionally engage said inwardly facing surface in the nose against said retraction force which is provided when the spring is compressed within the nose;

installing the retainer member on the head end of the needle holder;

loading the spring followed by the needle holder into the back opening in the barrel part of the syringe body and positioning at least the forward portion of the spring and a portion of the elongated body of the needle holder within the nose;

moving the head end of the needle holder and the coupled retainer member into the most constricted part of the transition zone where the nose begins; and

installing the coupled needle holder and retainer member in the nose by sliding engagement of the outwardly facing surface of the retainer member with the inwardly facing surface in the wall while compressing the spring within the nose.

18. The method of claim 17 further including the step of mounting a needle in the front of the elongated body portion in communication with the fluid path after the coupled needle holder and retainer member are installed in the nose.

19. The method of claim 17 further including the steps of providing a plunger assembly having a front portion and a back portion, the front portion including a head configured for sliding sealed contact with the interior of the outer body and installing the front portion of the plunger assembly into the barrel through the open back end.

20. The method of claim 17 wherein the step of installing the coupled needle holder and retainer member in the nose include the step of grounding the needle holder in the nose to prevent forward movement of the needle holder relative to the nose after installation.

21. The method of claim 20 wherein the needle holder is provided with a tip in front of the elongated body portion and the step of grounding the needle holder in the nose includes the step of causing the tip to project forwardly beyond the nose.

22. The method of claim 21 further including the step of mounting the needle in said tip of the needle holder in communication with the fluid path.

23. The method of claim 17 wherein the nose has a wall defining an internal cavity which closely confines the spring and needle holder combination and the step of positioning at least the forward portion of the spring includes the step of using this cavity as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring.

24. A method of assembling a tamperproof retractable syringe which is well suited for automated assembly;

providing a one piece hollow syringe body having a longitudinally extending wall with an open back end,

comprising an elongated barrel and nose portion of reduced cross sectional area relative to the barrel, and an inwardly facing surface in the wall at the most constricted part of a transition zone between the barrel and nose where the nose begins;

providing a plunger assembly having a front portion and a back portion, the front portion including a head configured for sliding sealed contact with the interior of the elongated barrel, said head having a retraction cavity and a leading end configured to contact and remove a retainer member from a needle holder to be mounted in the nose;

providing a needle holder having an elongated body portion in front and a head in back with a fluid path therethrough, the head of the needle holder having a retainer member which can be separated from the head of the needle holder by contact with the leading end of the plunger, the retainer member having an outwardly facing surface configured to slidingly and frictionally engage said inwardly facing surface in the nose and hold the needle holder against a retraction force provided by the spring when the spring is compressed within the nose;

loading the spring followed by the needle holder into the back opening in the barrel part of the syringe body and positioning at least the forward portion of the spring and a portion of the elongated body of the needle holder within the nose;

moving the head end of the needle holder and the retainer member into the most constricted part of the transition zone where the nose begins; and

installing the needle holder and retainer member in the nose by sliding engagement of the outwardly facing surface of the retainer member with the inwardly facing surface in the wall while compressing the spring within the nose.

25. The method of claim **24** further including the step of mounting a needle in the front of the elongated body portion of the needle holder in communication with the fluid path after the needle holder is installed in the nose.

26. The method of claim **24** further including the step of installing the front portion of the plunger assembly into the barrel through the open back end.

27. The method of claim **24** further including the steps of providing a dislodgeable stopper for said retraction cavity and installing it therein.

28. The method of claim **27** wherein said stopper is installed through an opening in the back portion of the plunger assembly.

29. The method of claim **28** wherein the step of installing said stopper includes the step of positioning a portion of said stopper behind and a portion of said stopper beyond the leading end of the plunger head.

30. The method of claim **28** further including sealing the back portion of the plunger assembly after the stopper is installed.

31. The method of claim **30** further including the step of installing the front portion of the plunger assembly into the barrel through the open back end.

32. The method of claim **24** wherein the step of installing the needle holder in the nose portion includes the step of grounding the needle holder to prevent forward movement of the needle holder relative to the nose after installation.

33. The method of claim **32** wherein the needle holder is provided with a tip in front of the elongated body portion and the step of grounding the needle holder in the nose includes the step of causing the tip to project beyond the nose.

34. The method of claim **33** further including the step of mounting the needle in said tip of the needle holder in communication with the fluid path.

35. The method of claim **24** wherein the nose has a wall defining an internal cavity which closely confines the spring and needle holder combination and the step of positioning at least the forward portion of the spring includes the step of using this cavity as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring.

36. A method of assembling a tamperproof retractable syringe which is well suited for automated assembly;

providing a one piece hollow syringe body having a longitudinally extending wall with an open back end, comprising an elongated barrel and nose portion of reduced cross sectional area relative to the barrel, and an inwardly facing surface in the wall at the most constricted part of a transition zone between the barrel and nose where the nose begins;

providing a needle holder having a fluid path, the needle holder having an elongated body portion in front and a head end in back, and providing a spring under the head end which circumscribes the needle holder;

providing a separable retainer member surrounding the head end of the retainer member sealingly and releaseably coupling the retainer member and said head end with a holding force sufficient to resist a retraction force provided to the needle holder by a compressed spring, the retainer member having an outwardly facing surface configured to slidingly and frictionally engage said inwardly facing surface in the nose and hold the needle holder against the retraction force when the spring is compressed within the nose;

loading the spring followed by the needle holder into the back opening in the barrel part of the syringe body and positioning at least the forward portion of the spring and a portion of the elongated body of the needle holder within the nose;

moving the head end of the needle holder and the coupled retainer member into the most constricted part of the transition zone where the nose begins; and

installing the coupled needle holder and retainer member in the nose by sliding engagement of the outwardly facing surface of the retainer member with the inwardly facing surface in the wall while compressing the spring within the nose.

* * * * *

EXHIBIT C

US006090077A

United States Patent [19]

Shaw

[11] Patent Number: 6,090,077

[45] Date of Patent: Jul. 18, 2000

[54] **SYRINGE PLUNGER ASSEMBLY AND BARREL**

[76] Inventor: **Thomas J. Shaw**, 1510 Hillcrest, Little Elm, Tex. 75068

[21] Appl. No.: **08/843,050**

[22] Filed: **Apr. 25, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/537,242, Sep. 29, 1995, Pat. No. 5,632,733, which is a continuation of application No. 08/438,954, May 11, 1995, Pat. No. 5,578,011.

[51] **Int. Cl.**[7] **A61M 5/00**

[52] **U.S. Cl.** **604/195**; 604/110; 604/218

[58] **Field of Search** 604/195, 198, 604/263, 110, 187, 218, 227

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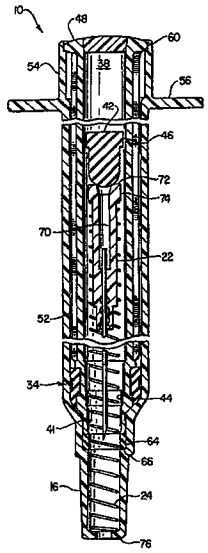
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Locke Liddell & Sapp, LLP

[57] **ABSTRACT**

A tamperproof retractable non-reusable syringe has a one piece hollow outer body with a barrel for a slidable plunger, a transition zone and a smaller diameter nose portion. An elongated needle holder and spring combination is installable from the rear of the outer body, guided into the nose portion and held by cooperating inwardly and outwardly facing surfaces oriented in the direction of retraction at the most constricted part of the transition zone where the nose begins. The plunger has an opening with a dislodgable stopper for receiving parts of the retraction mechanism. The stopper and the head of the needle holder are of significantly reduced diameter from the injection fluid chamber to resist blowing out prematurely. In one embodiment the head of the needle holder is surrounded by a separable retainer member which is slidingly removed by contact with the tip of the plunger after the stopper is mostly or fully removed to avoid cumulation of force required for retraction after the injection. In a second embodiment the head of the needle holder is clamped and held by constricting forces imposed by stress on the outer body induced by interference fit. Release occurs by slight expansion on the barrel by contact of the plunger tip with a small internal ramp in the outer barrel. Both embodiments have a plunger cap configured to enter an opening in the outer body to provide an additional tamperproof feature. The retraction cavity is provided with venting structures to assure that all uninjected fluid is retained within the syringe body.

41 Claims, 8 Drawing Sheets



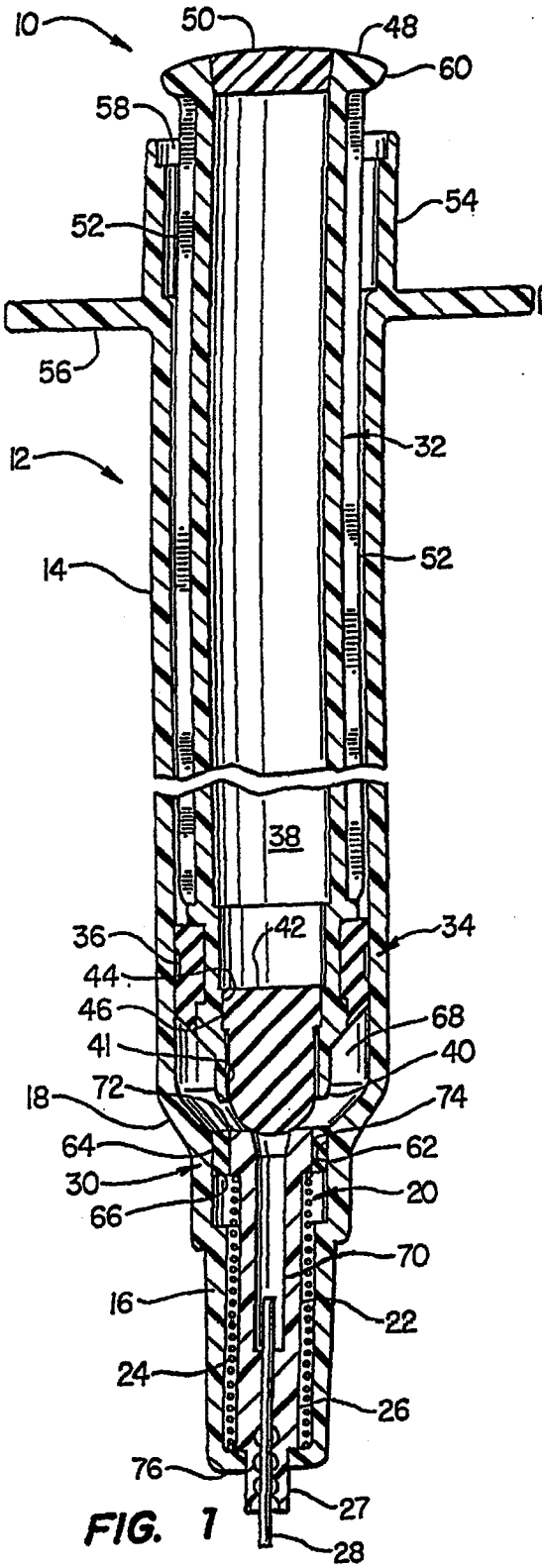

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FIG. 1

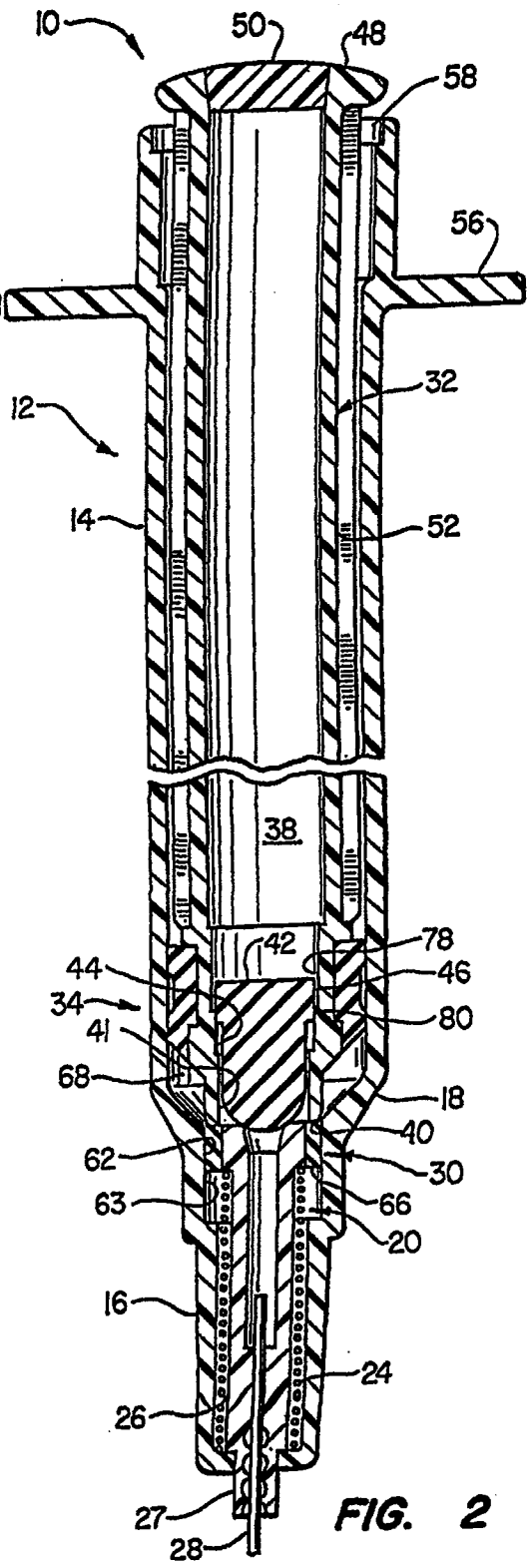
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FIG. 2

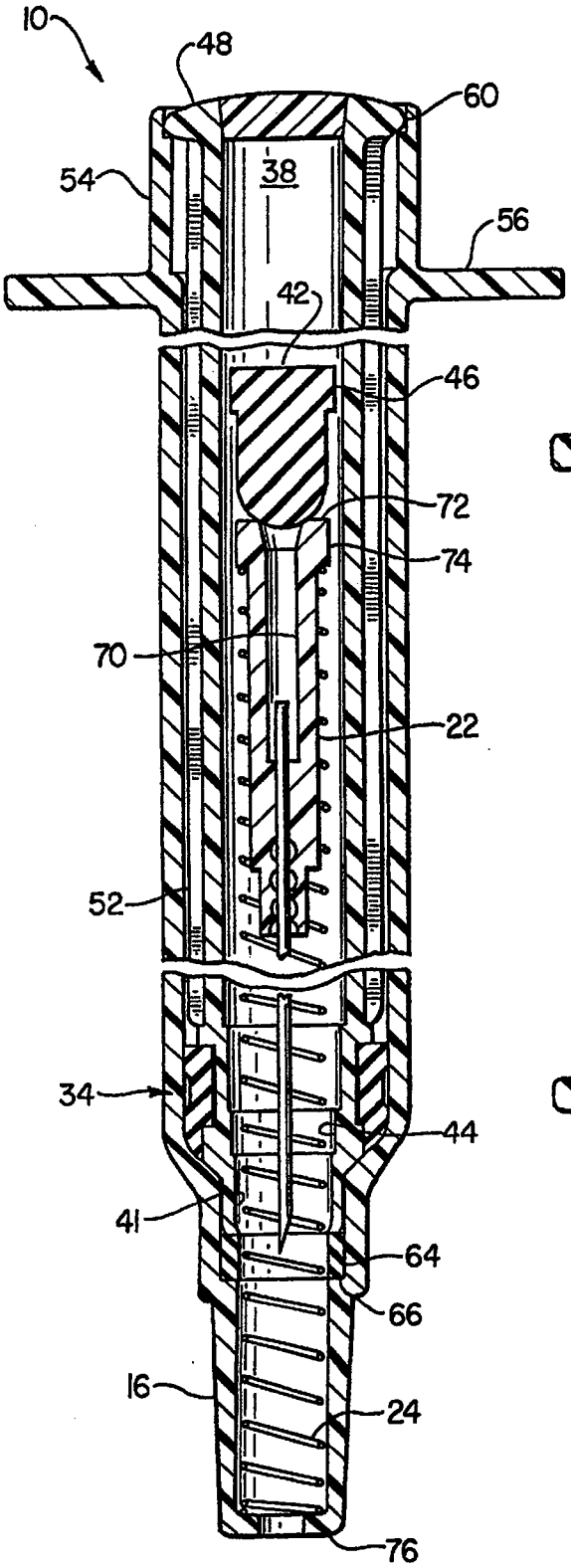


FIG. 3

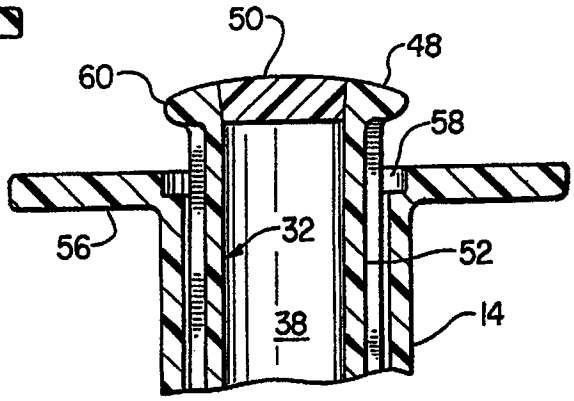
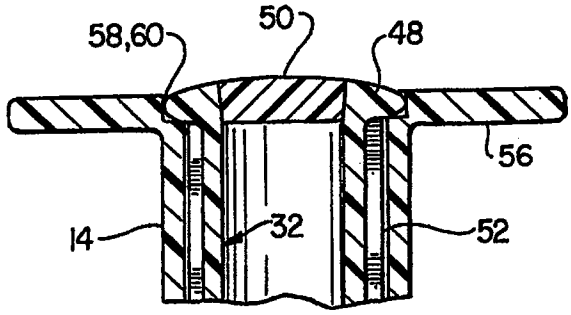


FIG. 4A



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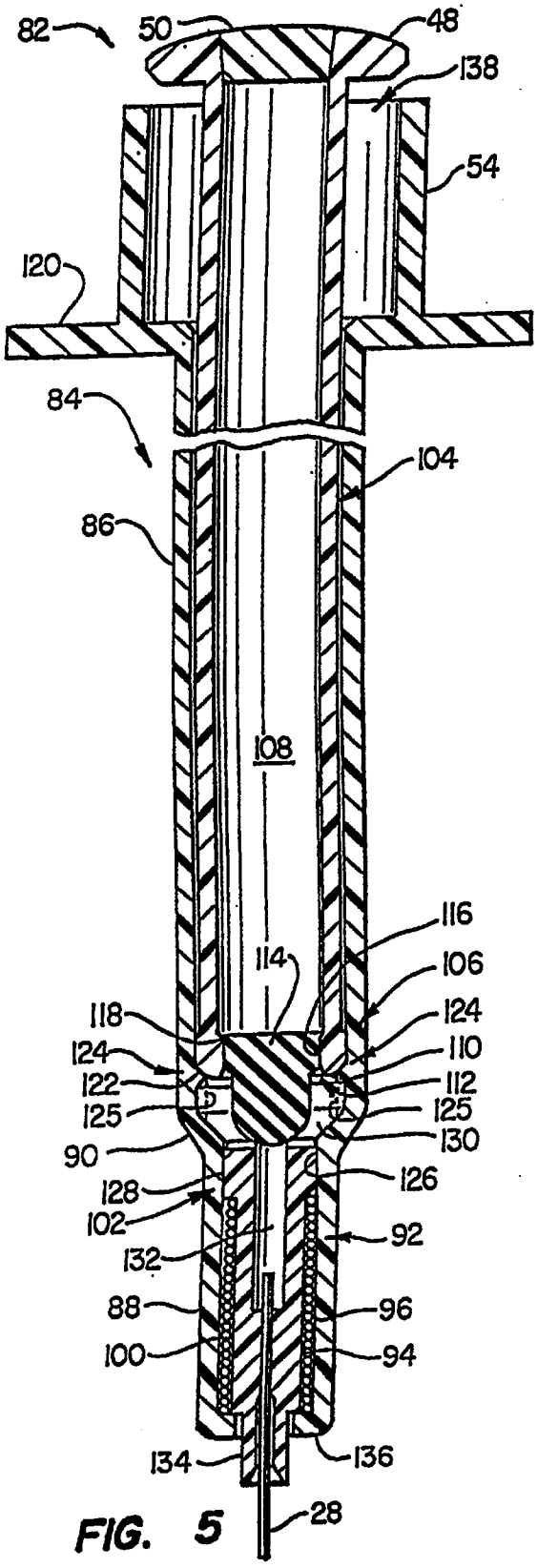
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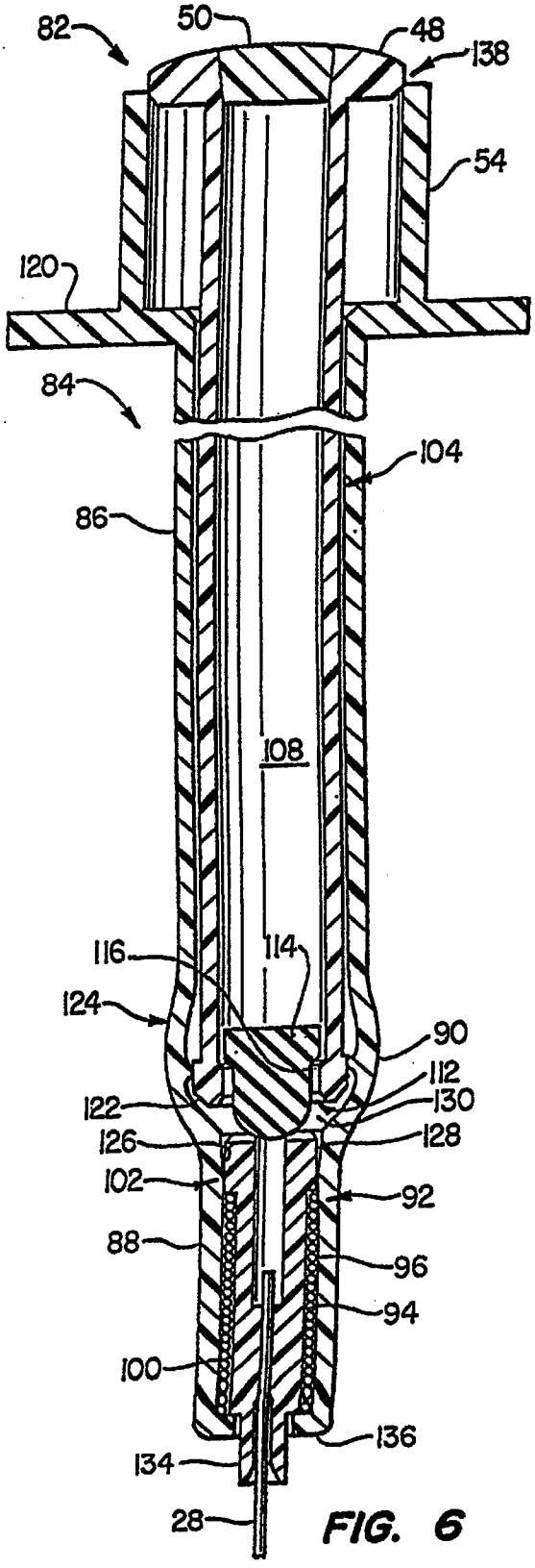
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FIG. 6

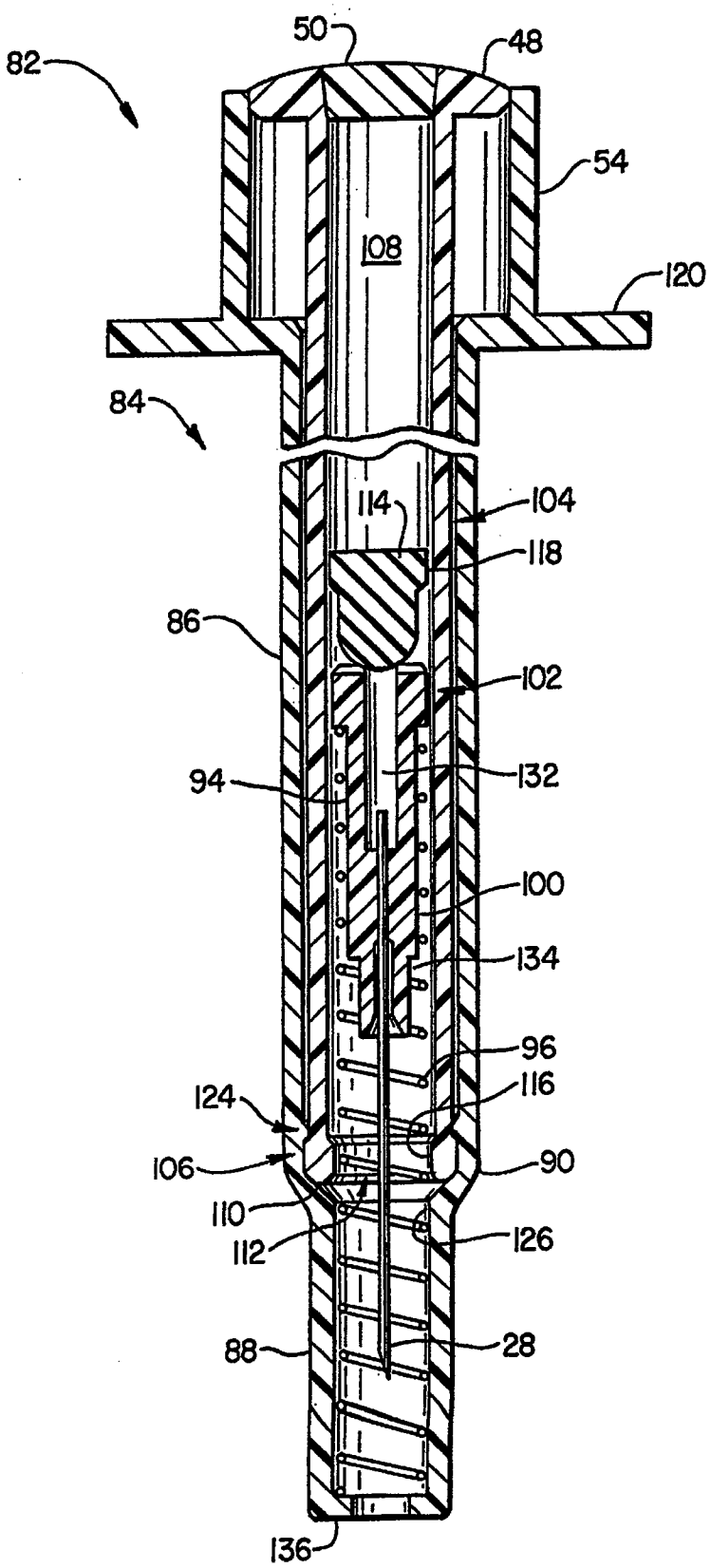
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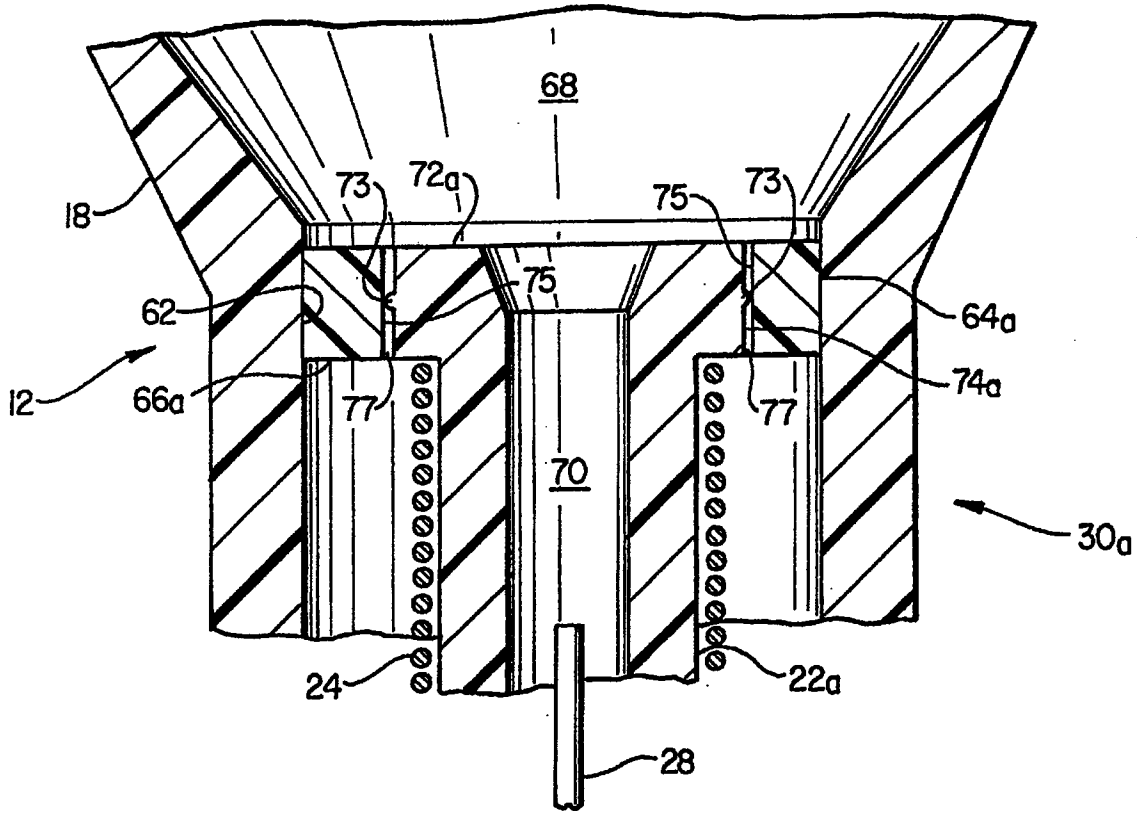
FIG. 7



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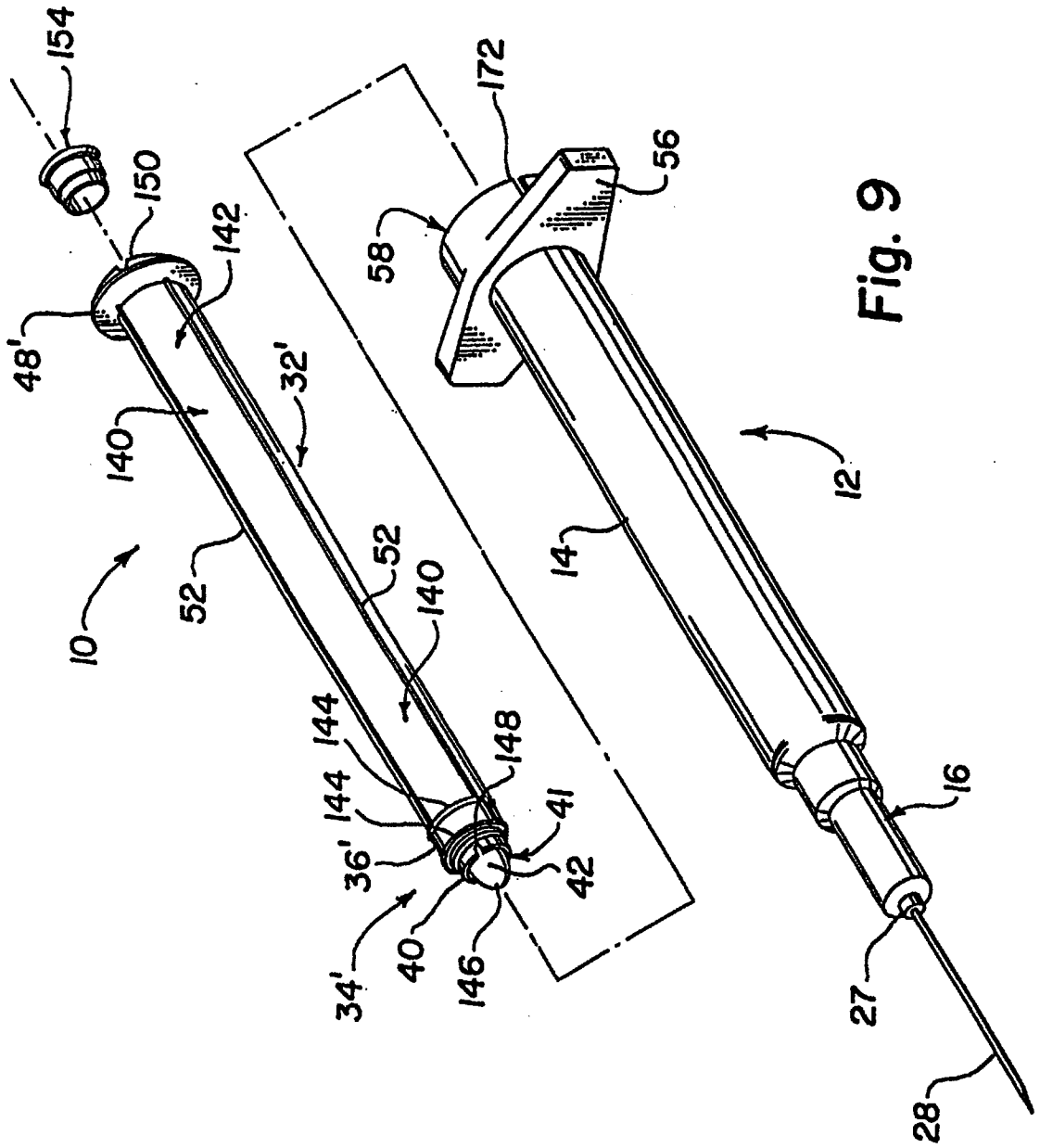
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Fig. 9

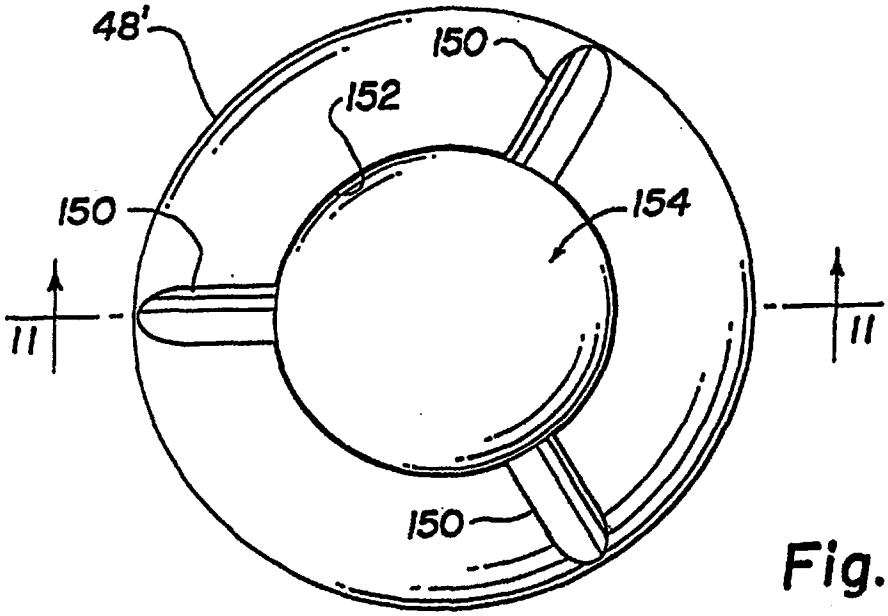
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Fig. 10

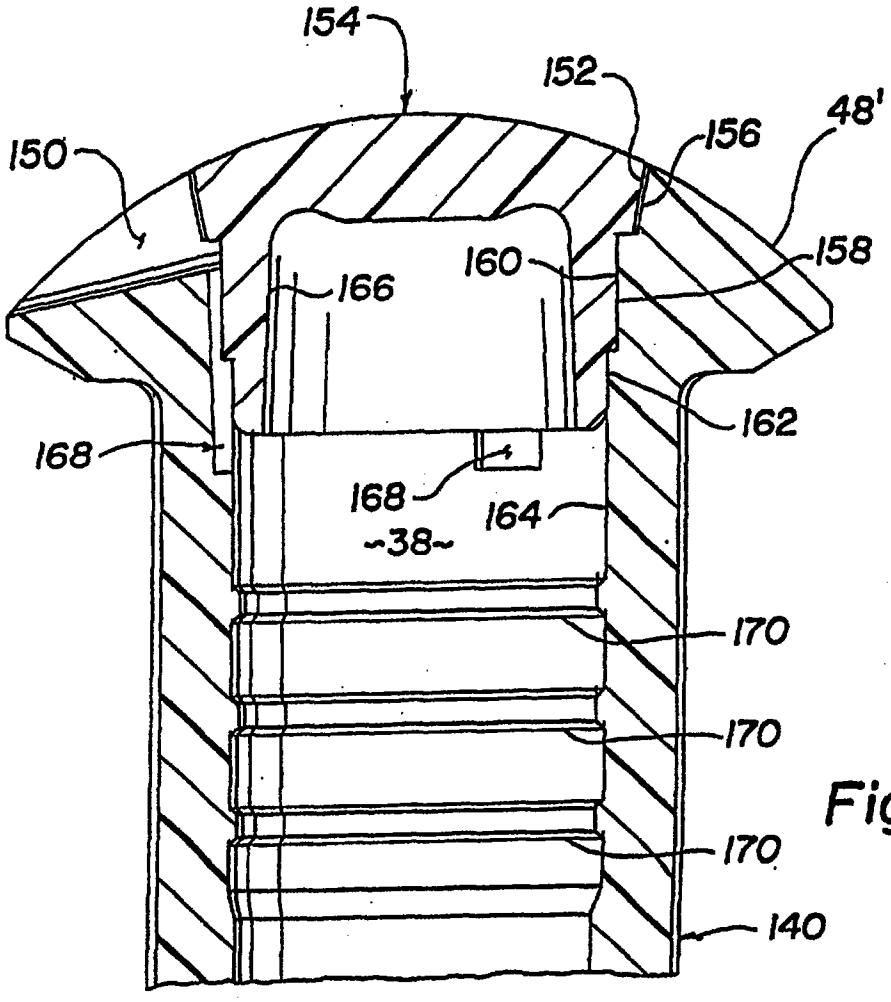
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Fig. 11

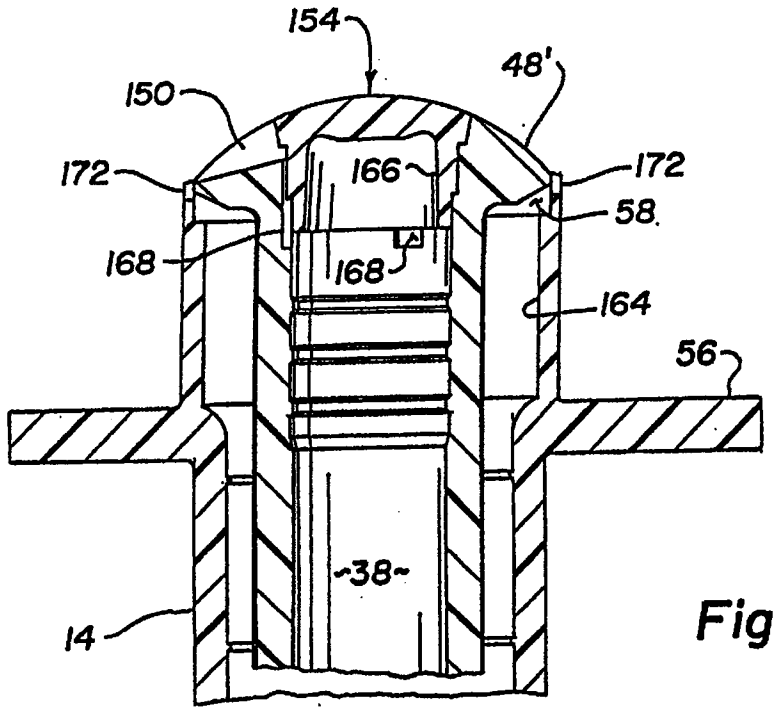

Fig. 12

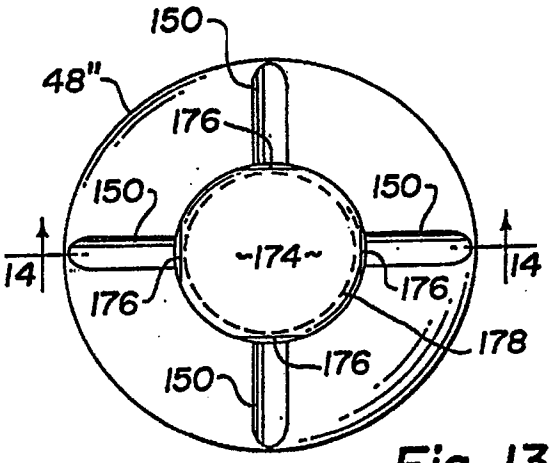

Fig. 13

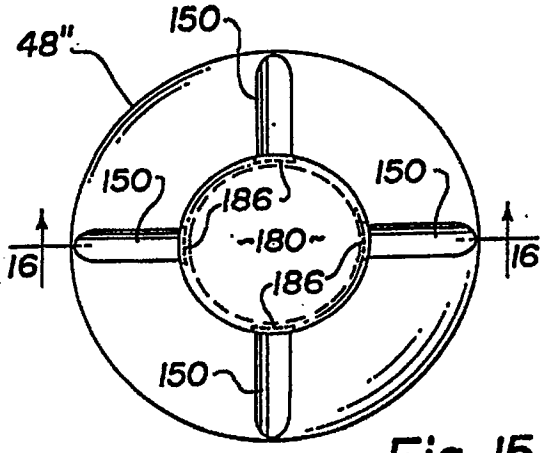

Fig. 15

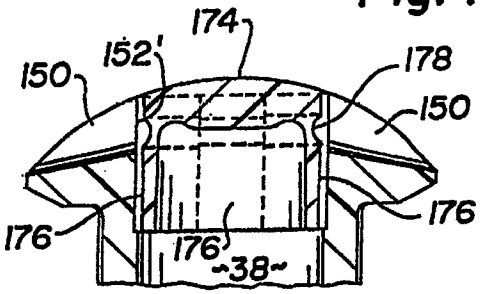

Fig. 14

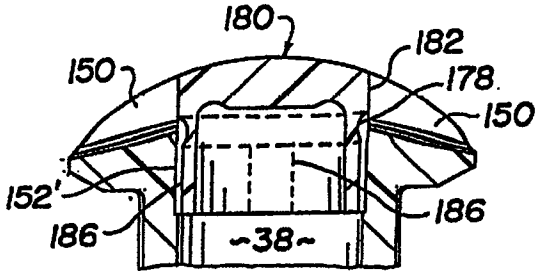

Fig. 16

SYRINGE PLUNGER ASSEMBLY AND BARREL

This is a continuation-in-part of patent application Ser. No. 08/537,242 now U.S. Pat. No. 5,632,733 filed Sep. 29, 1995 entitled Tamperproof Retractable Syringe which in turn was a continuation of Ser. No. 08/438,954 filed May 11, 1995, now U.S. Pat. No. 5,578,011 all by the same inventor for which benefit is claimed under 35 U.S.C. §120.

FIELD OF THE INVENTION

This invention relates to a medical device, and more particularly to a retractable syringe and components suitable for mass production and assembly having a low triggering force and high blowout pressure which is nonreusable after one use.

BACKGROUND OF THE ART

A major cause to the spread of AIDS in the general population is the presence of IV drug users who share and reuse hypodermic syringes to inject drugs. Infection can be spread from AIDS patients in hospitals and medical facilities through accidental needle sticks from needles used on infected patients. Used syringes with extended needles present a risk to medical personnel and sanitation employees and others in the disposal chain.

The gravity of the threat posed by AIDS and the fact that the main vector of the spread of the dreaded disease is through reuse of syringes by IV drug users has resulted in intense activity to develop the most practical, most reliable, easily assemblable, mass-producible syringe.

There are a number of syringes of different designs which have needles which will retract at the end of the injection cycle. Most of these have never reached the market because of various deficiencies. Prime among the usual deficiencies of the prior art are problems of complexity, reliability, cost and ease of use. The most commonly used syringes are 1 cc and 3 cc syringes which must be mass-produced at the rate of millions per day. Cost is a significant factor both in manufacture of the parts and assembly of the device. High speed production requires molds with 64 cavities or more to reduce unit cycle time. Therefore, molded structures within the barrel that require collapsing core pins such as are shown in much of the art are unlikely to be producible at competitive costs.

One of the problems of the prior art of retractable syringes is the sheer number and complexity of parts which must be formed and assembled. Other problems with the prior art are dependence on flexing or breaking of internal parts by the plunger in order to release the retraction mechanism and use of a diaphragm at the end of the plunger which must be penetrated by a needle holding member and spring. These structures present serious quality control and assembly problems. Small broken off pieces can present a risk of hang-ups. Hooks are often used to releaseably secure retraction mechanisms. Hooks present difficult holding and control problems, may cause retention of air bubbles upon filling and may be undesirably temperature sensitive.

The prior art frequently has a two-piece barrel in order to be able to assemble a retraction device in the nose. This requires at least an additional part and assembly step. It is still necessary to pass the sharp injection needle through a small opening often while compressing a spring before the two parts can be assembled. The tiny needles are produced in the form of coil tubing and vary significantly from straightness after they are cut to length. This leads to difficult assembly problems if the needle must be passed through a small opening. The extremely sharp tip will catch the edge of a hole and jam the production line.

The rare prior art that employs a front mounted retraction mechanism in a one-piece barrel with a plugged hollow plunger, Tsao U.S. Pat. No. 5,084,018, among other things does not show reduced barrel area to prevent excessive blowout pressure, employs engaging flanges to secure all retraction parts, requires concurrent distortion of internal parts and flanges to effect release, cumulating in excessive force required to retract and requires ventilation holes because of a compartmented barrel.

The prior art has not produced a retractable nonreusable tamperproof syringe for mass production and assembly which is simple, reliable, cost effective, easy to use and retract, looks like a conventional syringe, has few parts which are easy to make and assemble, is not temperature sensitive and not subject to danger of premature retraction.

The prior art has not recognized a retraction mechanism with separable parts that relies entirely on clamping force or friction at a smooth walled reduced diameter transition zone in the barrel with mating lands which are slidably or separably released in response to relatively low thumb pressure while having resistance to premature retraction and high blowout pressure resulting from high pressure produced in the fluid chamber during an injection. The prior art has not recognized that such a structure can be molded as a one piece outer body over a core that can be pulled out from behind allowing the retraction mechanism to be easily pushed into place from behind, steered by the narrow nose portion. Neither does the prior art in such a combination realize the desirable non-cumulation of forces resisting retraction in order to minimize the thumb force required, having a most simple tamperproof feature and the fewest number of easily made parts.

The syringe plunger assembly has a combination of features not found in a prior art syringe. A head end which acts like a piston when installed in a syringe barrel has a reduced diameter front end having an opening and a dislodgeable stopper slidingly mounted in the opening projecting forwardly from the tip. Cooperating lands within the opening and on the head of the dislodgeable stopper seal the opening into the hollow interior of the plunger. The area of the stopper is relatively small when compared to the area exposed to the piston, which compresses fluid in a chamber below the piston. The ratio of the total area of the fluid chamber to the fluid exposed area of the stopper is at least two to one, more preferably three to one or more so that the stopper requires less holding force without blowing out back into the internal cavity. The cooperating lands have sufficient length so that the stopper can move back to the tip when the plunger moves forward at the end of an injection stroke without unsealing the plunger opening. A reduced holding force is sufficient to prevent blowout of the stopper after the stopper has been moved back to the tip because the stopper is exposed to a lower pressure generated force because of its relatively smaller area. The back of the plunger is vented so that entry of retractable parts which upon retraction finish dislodging the stopper and carry it back into the cavity, do not generate internal pressure that can blow out the nose of the syringe carrying any residual fluid with it. The thumb cap on the plunger is received and recessed into the opening at the back of the barrel when retraction occurs. The plunger cannot be grasped after this occurs to help prevent reuse.

These features and more are found in the inventive combination herein further disclosed which is especially suited for high speed production and assembly at low cost.

SUMMARY OF THE INVENTION

The invention is a reliable retractable tamperproof syringe having multiple tamperproof features which operates on a principle which permits low cost parts which are few in number and well suited for high speed mass production and assembly. The syringe structure features a one piece hollow outer body having a longitudinally extending wall which is stepped. The wall comprises an elongated barrel and nose with a transition zone connecting the barrel and nose. The nose has a reduced diameter relative to the barrel. The outer body has an inwardly facing surface in the wall at the most constricted part of the transition zone where the nose begins. A plunger assembly is disposed partially within the elongated barrel with an end cap for depression of the plunger extending from an opening in the back of the barrel. The head of the plunger, which has a retraction cavity for receiving parts of a retraction mechanism, moves in slidable sealed contact with the interior of the barrel.

A retraction mechanism is lodged in the nose of the body. The retraction mechanism comprises an elongated needle holder and spring combination wherein the needle holder has an elongated body with a needle holding portion in front and a head in back. The head of the needle holder has a cooperating outwardly facing surface configured to cooperate with said inwardly facing surface along an interface oriented in the direction of retraction to produce a holding force on the needle holder when installed in the nose in the unretracted position. The needle holder and spring are easily installable from the rear of the barrel toward the nose and releaseably held by sliding engagement of said cooperating inwardly and outwardly facing surfaces while compressing the spring and thereby producing a holding force on the needle holder in opposition to the retraction force applied to the needle holder by the spring. The parts are circular in cross section.

The outwardly facing surface on the circular head of the needle holder is slightly greater in diameter than the circular inward facing surface in the wall at the most constricted portion where the nose begins. The needle holder is thus clamped in position by hoop stresses induced in the outer body and held in position by frictional holding force. The needle holder is released in response to depression of the plunger to a retraction position. Retraction occurs in response to thumb force on the plunger when a portion of the plunger passing into the transition zone separates at least a portion of the inwardly and outwardly facing cooperating surfaces thereby reducing the holding force on the needle holder to an amount less than a retraction force on the needle holder produced by the spring whereby the needle holder is retracted into the cavity a distance sufficient to withdraw an injection needle, attached to the needle holder, into the outer body.

In one embodiment, the head of the needle holder is a two part head comprising an inner head surrounded by a separable retainer member wherein the outer surface of the retainer member is the outwardly facing surface with cooperates with the inwardly facing surface in the wall to retain the needle holder in an unretracted position at the most constricted part of the transition zone where the nose begins. The retainer member is a ring member coupled to the inner head along a sliding interface oriented in the direction of retraction with a friction force which exceeds the retraction force provided by the spring. The front of the needle holder is grounded in the nose portion against forward movement. The plunger head is configured to pass through the most constricted area and push against the retainer member without also pushing against the head of the needle holder. An alternate construction of the two part head of the needle holder comprises the separable retainer member being tack welded to the inner head of the needle holder, preferably along a very small ridge or bridge between the mating surfaces which holds the two part head together until the bridge is ruptured by movement of the plunger after an injection has occurred.

The front of the plunger has an opening for a stopper slidingly fitted therein in an interference fit. The stopper is fitted in the opening in an interference fit along a sliding interface oriented in the direction of retraction. The stopper is mostly or fully dislodged by contact with the retraction mechanism at the end of an injection cycle by continued depression of the plunger from a first position at the end of the injection cycle to a second position with the tip of the plunger in contact with the retainer ring. This avoids cumulation of the force on the plunger required to dislodge the stopper from the opening and the force required to dislodge the retainer member from the head of the needle holder and outer body wall. Upon further depression of the plunger from the second position to the retraction position, the frictional holding force on the needle holder is reduced until the retraction force provided by the spring exceeds the remaining holding force and the needle holder and needle connected thereto are ejected into the cavity carrying the dislodged stopper along with them. The dislodging of the stopper and the retainer member alone make the syringe non-reusable. The plunger cannot be removed after retraction because the graspable end cap enters an opening at the back of the barrel when the plunger is depressed to the retraction position to prevent tampering after retraction.

The retraction cavity of the plunger is preferably vented to prevent a puff of air coming forward at the instant of retraction from blowing a tiny amount of retained fluid from the nose. This condition can occur if the plunger is fully depressed to release the needle holder and dislodge the stopper while the needle is physically restrained from retracting by the septum of a vial which has just been filled with fluid from the syringe. The thumb cap at the rear of the syringe is preferably provided with channels in fluid communication with the interior in cooperation with a closure removably installed in a centrally located opening in the thumb cap. One or more stepped portions of the opening and closure provide seating for the closure. Undercut portions at the side of the closure together with grooves in the interior surface of the plunger wall create passages for air to vent through channels on the thumb cap. This structure prevents air from being trapped by the user's thumb when the thumb cap is pressed to fire the syringe. One or more slots at the back of the barrel around the opening which receives the thumb cap prevent vented air from being trapped by the user's thumb when the plunger is fully depressed.

The syringe has a high blowout pressure and a low plunger thumb force required to cause retraction. Blowout pressure is the fluid pressure operating on the stopper and retainer ring during an actual injection. High blowout pressure resistance is obtained because the retainer ring is mounted in the most constricted portion of the barrel where the nose begins which significantly reduces the amount of area exposed to fluid pressure. The smaller retainer ring allows the use of a small needle holder such that the opening in the plunger and the stopper can be only a fraction of the cross sectional area of the fluid chamber below the plunger head. The ratio of the greatest cross sectional area of the variable chamber and that of the dislodgeable stopper or the ring member are selected so that the maximum expected

thumb force on the plunger during an injection will produce a maximum pressure in the chamber which will generate a blowout force on the stopper and retainer member slightly less than the amount of dislodging force necessary to dislodge the stopper and retainer member during retraction. This ratio should be at least two to one, or more preferably three to one or more, in order to ensure against premature blowout of the stopper or retainer ring.

In an alternate embodiment, the fewest number of easily made separate parts are used in a retractable syringe. The alternate embodiment has a similar stopper in the head of the plunger and a similar needle holder and spring combination with mating cooperating inwardly facing and outwardly facing interengaged surfaces at the most constricted part of a transition zone where the nose begins. In the alternate embodiment, there is no retainer ring around the head of the needle holder. Instead a tiny ramp is provided at the transition zone or adjacent the transition zone whereby the head of the plunger gently spreads the barrel outwardly while dislodging the stopper thereby reducing the clamping or friction force on the head of the needle holder provided by the wall of the outer body. The holding force is thereby reduced below the retraction force provided by the compressed spring and the needle holder is ejected into the cavity of the plunger carrying the dislodged stopper along with it.

Manufacture and assembly is facilitated by the fact that the plunger and the outer body can be molded with a non-collapsible core tool that can be pulled out from behind. The parts are simply shaped and do not have hooks and parts with reentrant angles that require collapsible core pin technology. The outer body can be made in one piece and assembled from the rear. The narrowed nose portion provides no lateral space with will permit bunching of the spring and jamming when the retraction assembly is moved forward in the outer body. In fact, the nose serves as a guide to steer the parts into the proper position in one smooth stroke.

The needle does not have to be installed before the retraction mechanism is put in place because it is readily installed from the front after the needle holder is slidingly lodged in the nose. Significant variations in the holding force on the needle holder and the dislodging force on the stopper due to slight variances in the tolerance of the mating parts is avoided because the longitudinal wall of the outer body has some flexibility. The wall can spread outwardly slightly and the stopper and head of the needle holder can compress slightly radially and expand slightly in the longitudinal direction to avoid significant changes in the holding force caused by small changes in the actual diameters. Consistency in the amount of retraction force is thereby provided and economy is assured.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross section along the central axis of a first embodiment of the invention with the plunger positioned in a first position at the end of an injection cycle;

FIG. **2** is the syringe of FIG. **1** with the plunger depressed additionally to dislodge the stopper at a second position of the plunger wherein the tip of the plunger is ready to operate the retraction mechanism;

FIG. **3** is the syringe of FIG. **2** wherein the plunger has been further depressed to a retraction position, retraction has occurred and the cap at the back of the plunger is closely received in an opening at the back of the outer body;

FIG. **4A** is a partial cross section on the central axis of an alternate tamperproof opening in the back of the outer body prior to retraction;

FIG. **4B** is the structure of FIG. **4A** with the plunger in the retracted position received in an opening at the back of the outer body;

FIG. **5** is a cross section along the central axis of a simplified alternate syringe structure without a retainer member around the needle holder, which is released by separation of the friction surfaces, shown in the plunger position which represents the end of an injection cycle;

FIG. **6** is the syringe structure of FIG. **5** wherein the plunger is further depressed to dislodge the stopper and begin to release the friction surfaces just prior to retraction;

FIG. **7** is the syringe structure of FIG. **6** with the plunger further depressed beyond the position of FIG. **6** to the retraction position where retraction has occurred and the cap is secure within an opening in the back of the hollow outer body.

FIG. **8** is a schematic longitudinal cutaway view in elevation through the center of the two part head showing how a tack weld can be applied to simultaneously seal and hold the retainer ring in place on the needle holder.

FIG. **9** is an exploded perspective view showing the barrel and retraction mechanism of FIG. **1** with a modified plunger assembly;

FIG. **10** is a plan view of the thumb cap of the plunger assembly shown in FIG. **9** with the preferred closure;

FIG. **11** is a cut away elevational view of the structure at the back end of the plunger and end cap of FIG. **9** and **10** along line **11**—**11** showing the preferred closure;

FIG. **12** is a cut away elevational view of the plunger end cap and closure of FIG. **11** as the thumb cap is just being received into the barrel opening;

FIG. **13** is a plan view of a first alternative thumb cap and closure combination utilizing a flat sided closure and four channels in the thumb cap;

FIG. **14** is a cut away elevational view on the lines **14**—**14** of the thumb cap closure combination of FIG. **13**;

FIG. **15** is a plan view of a second alternate thumb cap and closure combination with four channels in the thumb cap and undercut portions to provide a vent passage;

FIG. **16** is a cut away elevational view on the lines **16**—**16** of the combination of FIG. **16**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the description that follows, like parts will be referred to by the same reference numerals. Parts with a subscript letter are mean to illustrate a minor variation of a part with the same number. The drawings are enlarged significantly in order to show the details of the invention but generally reflect the true scale which is contemplated. The parts as shown are understood to be preferably circular and symmetrical as is conventional for syringes. The drawings reflect a syringe structure typically having a 1 cc to 3 cc injection fluid capacity.

FIG. **1** shows the structure of the first embodiment generally referred to by reference numeral **10**. Syringe **10** has a one piece hollow outer body **12**. Body **12** has a longitudinally extending wall comprising an elongated barrel **14** and a nose **16** with a transition zone **18** connecting the barrel and nose. A front mounted retraction mechanism lodged in the nose is generally referred to by the reference numeral **20**. It comprises the combination of an elongated needle holder **22** and spring **24**. The needle holder has an elongated body with a needle holding portion **26** in front for holding a needle **28**

and a head **30** in back. Head **30** may consist of a two part head as in FIGS. **1–3** or a one part head as in FIGS. **5–7**. The needle holder is released by depression of a plunger that win be described.

A plunger generally designated by the reference numeral **32** is disposed for use partially within barrel **14**. The plunger has a head and seal generally referred to by reference numeral **34**, in slidable sealed contact with the interior of barrel **14** of outer body **12**. The plunger has a seal element **36** that is conventional and a retraction cavity **38** therein.

Head **34** has a tip portion **40** forming an opening **41** into retraction cavity **38**. A resilient dislodgable stopper **42** is sealingly positioned in opening **41** with a front portion thereof extending beyond tip **40**. Head portion **34** and the back part of stopper **42** have cooperating lands **44, 46**, respectively, which seal opening **41**. Plunger **32** has an end cap **48** for depression of the plunger by the thumb. End cap **48** has a central opening for permanently receiving force fit plug **50** to close retraction cavity **38** at the back end.

A plurality of longitudinally extending flutes **52** slidingly support plunger **32** in barrel **14**. In the embodiment of FIG. **1**, outer body **12** has a collar **54** extending behind finger grips **56** having opening **58** which closely receives the outer periphery **60** of cap **48** when the plunger is depressed to the retracted position. An alternate arrangement is shown in FIGS. **4**A and **4**B in which barrel **14** is extended longitudinally, if necessary, so that end cap **48** fits closely within an opening at the back of the barrel where the finger grips are. FIG. **4**B shows the tamperproof position with the plunger in the retracted position. It should be noted that depending on the relationship of the inside diameter of the barrel and the diameter of the end cap, the end cap could instead be received right inside the opening at the back of the barrel. Regardless of how the end cap in back of the outer body and barrel are configured, the plunger can no longer be grasped after retraction has occurred because end cap **48** is depressed into an opening.

The wall of outer body **12** and head **30** of the needle holder have mating cooperating smooth surfaces which hold needle holder **22** in the position shown in FIG. **1** with spring **24** compressed. Nose **16** has a reduced diameter relative to the barrel. The outer body has a most constricted part where head **30** of needle holder **22** is engaged and held. The outer body has an inwardly facing surface **62** at the most constricted part of the transition zone where nose **16** begins. Similarly, head **30** has an outwardly facing surface **64** configured to cooperate with inwardly facing surface **62** to produce a holding force on needle holder **22** when the retraction mechanism is installed in the nose from the rear. Mating surfaces **62, 64** constitute a sliding interface oriented in the direction of retraction, which seals nose **16**. Mating surfaces **62, 64** are preferably friction surfaces which have an interference sliding fit to apply a frictional holding force which holds needle holder **22** in position by friction between the mating parts. It is within contemplation of the invention that one or more of the cooperating interface surfaces could employ a coating or adhesive bond which is ruptured or released when the mating surfaces or lands are separated or moved relative to each other.

Head **30** provides a lower boundary for a variable fluid chamber **68** below head **34**. Needle holder **22** has a fluid path **70** in fluid communication with fluid chamber **68** and needle **28**. Needle holder **22** has a smaller diameter inner head **72** which is part of head **30**. Retainer member **66** is coupled to inner head **72** along sliding interface **74** oriented in the direction of retraction. Retainer member **66** is coupled to inner head **72** with a holding force which exceeds a retraction force applied to the underside of inner head **72** by means of the end of compressed spring **24**. A reduced diameter portion **27** of needle holder **22** protrudes through an opening in front **76** of nose **16**.

Importantly, retainer member **66** can be visualized as an annular ring surrounding circular inner head **72**. The location of retainer member **66** at the most constricted part of the transition zone where the nose begins and the relatively small area exposed to pressurized fluid in chamber **68** results in a high blowout pressure. Since the front portion **26** of the needle holder is grounded or bottomed inside front **76** of nose **16**, no amount of pressure will allow needle holder **22** or needle **28** to move forward. Blowout pressure may be defined as the pressure in chamber **68** acting on the exposed area of retainer member **66** to produce a force sufficient to overcome the holding force such that retainer **66** could "blowout" by moving forward and prematurely release needle holder **22**.

Some users have strong hands and might, at the outer limit in an emergency, be able to generate a force of as much as fifteen to eighteen pounds on the plunger during an injection. It is considered almost impossible for anyone to exert a force of more than eighteen pounds. This may be regarded as the maximum expected force which must be taken into account so that ring member **66** will not blowout while an injection is being made. The greatest cross sectional area of variable chamber **68** and the area of retainer member **66** exposed to fluid pressure are selected so that the blowout pressure is higher than the maximum pressure in chamber **68** expected to result from the maximum expected thumb force applied to cap **48** during an injection. This ratio is preferably about two to one and more preferably about three to one or more so that the holding force holding the retraction mechanism in place can be kept at a comfortably low level while the blowout pressure remains high.

Dislodgeable stopper **42** has a similar blowout problem to recognize. The front and middle portion of stopper **42** are relieved slightly from opening **41** such that the fluid pressure in chamber **68** is directed against the cross sectional area at cooperating lands **44, 46** and could cause stopper **42** to blowout. A frictional holding force is generated at the lands **44, 46** which may be called a dislodging force which must be overcome to slide stopper **42** rearwardly before retraction. The ratio of the maximum cross sectional area across the interior of variable chamber **68** to the maximum cross sectional area of stopper **42** exposed to pressure in chamber **68** are selected so that the maximum expected thumb force on plunger **32** during an injection will produce a maximum force slightly less than the amount of dislodging force necessary to dislodge the stopper so that stopper **42** will not blowout during an injection. This ratio is preferably not less than about two to one, more preferably three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds, respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The stopper is dislodged after the injection by thumb force applied to the stopper by movement of the plunger.

The components used for retraction are arranged to avoid cumulation of force during the retraction sequence. In FIG. **1**, stopper **42** has a forward extension beyond tip **40** which allows full thumb pressure to be applied to the stopper before any other portion of the retraction mechanism is engaged. The amount of forward extension beyond tip **40** is

related to the length of lands **44, 46** such that the forward extension of stopper **42** preferably represents about 80 percent of the engaged land length. When stopper **42** is moved back until the front is even with tip **40**, as seen in FIG. **2**, only about 20 percent of engaged land remains. In FIG. **2** it can be seen that thumb force on plunger cap **48** has been applied to partially dislodge stopper **42** such that a gap **78** is created and the remaining engaged land area is represented as area **80**.

Since I believe the amount of frictional holding force or dislodging force is roughly proportional to the amount of the length of the sliding interface between cooperating lands **44, 46**, it follows, ignoring dynamic effects, that the amount of force remaining decreases as the engaged sliding interface area is reduced. This is what happens as stopper **42** moves back into cavity **38** from the position of FIG. **1** to the position of FIG. **2**. It is believed appropriate to set the initial dislodging force to allow about five pounds at the position of FIG. **1** which is reduced to about one pound remaining when the stopper or plug member **42** reaches the position of FIG. **2**. It might be noted at this point in the description that the front portion of tip **40** preferably has some longitudinally extending slits or openings so that fluid is not trapped in the trapezoidal shaped area of chamber **68**, seen in FIG. **2**, because of contact between tip **40** and the upper surface of retainer ring **66**.

Needle holder **22** and spring **24** are combinably installable from the rear of the barrel before the plunger is assembled and releasably held at the most constricted part of the transition zone where the nose begins by sliding engagement of the cooperating inwardly and outwardly facing friction surfaces **62, 64** while compressing spring **24**. The length of the engaging land **64** and the amount of interference fit is preferably designed to provide a frictional holding force in opposition to the retraction force provided by the compressed spring **24** of somewhere around five pounds even though the spring may apply a retraction force in the retraction direction of somewhere around a half pound. In use the needle is pushed against a rubber seal in a vial so the needle holder must resist a resulting backward force without being dislodged during the filling operation. This requirement and blowout pressure limits the low end of the holding force on the needle holder.

Referring again to FIG. **2**, it can be seen that further depression of the plunger beyond the second position of FIG. **2** dislodges retainer ring member **66** along the sliding interface **74** provided by the outer surface of inner head **72** and along the inwardly facing friction surface **62**. As the amount of remaining engaged interface is reduced, the amount of force required to continue moving retainer member **66** off needle holder **22** is reduced and the small remaining engagement area **80** between lands **44, 46** of the plunger and stopper preferably cause stopper **42** to be dislodged before needle holder **22** is released. When the remaining residual friction force during continued depression of the plunger becomes less than the retraction force provided by compressed spring **24**, the retraction position of FIG. **3** is reached whereby retraction occurs.

When retraction occurs needle holder **22** moves through opening **41** into cavity **38**. The uncompressed length of spring **24** is selected to provide backward movement sufficient to withdraw an injection needle **28** fixed in front portion **26** entirely within outer body **12**, carrying dislodged stopper **42** with it. At the same time, cap **48** enters opening **58** of the barrel with peripheral edge **60** closely confined, in order to prevent tampering after retraction. It is immaterial whether cap **48** moves into the opening at the instant of retraction or after retraction has already occurred because the movement is automatic due to the continued thumb force applied to trigger the retraction. Sufficient unengaged length of inwardly facing friction surface **62** is provided so that retainer member **66** can move downwardly a sufficient distance to reach the retraction position of FIG. **3**. After retraction, retainer member **66** preferably remains stuck and prevents any possibility of any one being able to reengage it with the head of needle holder **22**. The diameter of land **62** in the area designated **63** can be increased slightly to provide relief for retainer ring **66** as it is pushed down by tip **40**.

It is also within the contemplation of the invention that separable retainer member **66** may be removably coupled to inner head **72** of needle holder **22** by means of a relatively small in area "tack" weld which is sufficient to resist the retraction force applied to needle holder by spring **24** but which can be ruptured or separated by depression of the plunger beyond the position shown in FIG. **2**, to release the needle holder and allow retraction. This is schematically illustrated in FIG. **8** with respect to alternate head **30***a* with the parts of syringe body **12** and needle holder **22** cutaway to focus on the modification. The remainder of the syringe structure would be like FIGS. **1–3**.

In FIG. **8**, inner head **72***a* has an outwardly facing surface **74***a* and a very small raised portion or series of horizontally spaced apart raised portions **73** around the periphery in a continuous band or annular ring which extend relatively uniformly outwardly beyond peripheral surface **74***a* of head **72***a*. The raised portion could be on the inner surface **75** of retainer **66***a* instead of being on surface **74***a* of the needle holder. The head of the needle holder is preferably circular but could be conceivably another shape with the retainer member **66***a* correspondingly configured to conform to it.

The inwardly facing surface **75** of inner head **72***a* is in contact with raised portion **73** on the outer surface of inner head **72***a* and there may be a small gap **77** between them all around. The raised portion **73** couples retainer **66***a* to inner head **72***a* and may be referred to as a bridging portion which resists the blowout pressure referred to above and holds the needle holder in place against the retraction force imposed on the needle holder by spring **24** together with any small additional forces that may be applied when the needle is pushed against the rubber seal of a vial in preparation for use. The bridging portion may be formed by "tack" welding the raised portion **73** to the inner surface of the ring **66***a* or by providing any other form of frangible bridging portion that holds the separable ring member **66** and needle holder head **72***a* together. It is required that however done, the bridging portion must also serve as a seal between the facing surfaces of the ring member and inner head so that fluid under pressure cannot pass from chamber **68** through gap **77** to reach the nose portion of the device. All fluid must pass through fluid passage **70**.

It can be seen that when the position of FIG. **2** is reached the front tip **40** of the plunger presses against retainer ring **66***a* after stopper **42** is almost dislodged and uncouples the retainer ring **66***a* from the inner head **72***a* of needle holder **22***a*. Any tack weld connecting the separable parts at the bridging portion is ruptured, fractured or otherwise separated so as to separate retainer ring **66** a from inner head **72***a* thus releasing needle holder **22***a* from further restraint. They and the force applied by spring **24** causes retraction to occur much as before described and shown in FIG. **3**.

It is believed that the increased diameter of the raised portion **73** should be within the range of about 1 to 8 thousandths of an inch which may be dictated by the ability

of the molding equipment available to produce a consistent bridging portion without defects. It is believed that it may be desirable to employ different polymeric materials for the retainer ring and needle holder to facilitate tack welding, such as a suitable polyvinyl chloride (PVC) for the retainer ring and a suitable polycarbonate plastic material for the needle holder. One way to couple these two parts may be to assemble them and expose them to a temperature of about 120° C. for twenty minutes or so to allow some diffusion or incipient melting to occur where they touch. The raised portion creates a high unit pressure where it comes into contact with the inwardly facing surface of retainer **66***a*. Sonic welding could also be employed. A coating or adhesive which couples the retainer ring to the needle holder and can be uncoupled by means of force applied to the retainer ring by the plunger is also within the contemplation of the invention.

An alternate syringe **82** is disclosed in FIGS. **5–7**. In FIG. **5**, Syringe **82** has a one piece hollow outer syringe body **84**. Body **84** has a longitudinally extending wall comprising an elongated barrel **86** and a nose **88** with a transition zone **90** connecting the barrel and nose. A front mounted retraction mechanism lodged in nose **88** is generally referred to by the reference numeral **92**. It comprises the combination of an elongated needle holder **94** and spring **96**. The needle holder has an elongated stem body with a needle holding portion **100** in front for holding needle **28** and a head **102** in back. In this case, head **102** is a one part head integral with the rest of needle holder **94**. Spring **96** delivers a retraction force in a retraction direction to the underside of head **102**.

A plunger generally designated by reference numeral **104** is disposed for use partially within barrel **86**. Plunger **104** has a head portion **106** which moves in slidable sealed contact with the interior of barrel **86** of outer body **84**. Although a separate seal might be used on head **106**, this embodiment is suitable for a smaller diameter, such as a 1 cc syringe, and can be used with head **106** also serving as the seal. A retraction cavity **108** is provided in the interior of hollow plunger **104**. Head **106** has a tip portion **110** forming an opening **112** for a dislodgable stopper **114** having a front portion extending beyond tip **110**. Head portion **106** has an inwardly facing land **116** and the back of stopper **114** has an outwardly facing land **118** comprising cooperating friction surfaces which seal opening **112**. The back portion of outer body **84** may have finger grips **120** and the same collar **54** and end cap **48** previously disclosed. The alternate arrangement of FIGS. **4A** and **4B** may also be employed.

The outer portion of tip **110** may be equipped with an angled surface **122** designed to cooperate with a small ramp surface **124** located in the vicinity of transition zone **90**. The wall of outer body **84** and head **102** of the needle holder have mating cooperating friction surfaces which frictionally hold needle holder **102** in the position shown in FIG. **5** with spring **96** compressed. Nose **88** has a reduced diameter relative to barrel **86**. The outer body has a most constricted part where the head **102** of needle holder **94** is frictionally engaged. The outer body has an inwardly facing surface or land **126** at the most constricted part of the transition zone where nose **88** begins. Similarly, head **102** has an outwardly facing friction surface **128** configured to cooperate with inwardly facing surface **126** to produce a frictional holding force on needle holder **94** when the retraction mechanism is installed in the nose from the rear.

Mating surfaces **126, 128** constitute a sliding interface oriented in the direction of retraction, which seal nose **88**. Mating surfaces **126, 128** are preferably smooth friction surfaces which have an interference sliding fit when needle holder **94** is installed from the rear whereby a frictional holding force holds needle holder **94** in position by friction between land **126** and head **102** of needle holder **94**. It is within contemplation of the invention that one or both of these surfaces could have a coating or adhesive bond which is ruptured when the mating surfaces are separated to release the needle holder.

Head **106** provides the upper boundary for a variable fluid chamber **130** below head **106**. Needle holder **94** has a fluid path **132** in fluid communication with chamber **130** and needle **28**. Needle holder **94** is releasably coupled at surfaces or lands **126, 128** with a holding force that exceed the retraction force applied to the underside of head **102** by the end of compressed spring **96**. A reduced diameter portion **134** of needle holder **94** protrudes through an opening in front **136** of nose **88**. Blowout pressure is not a factor with respect to the needle holder on the alternate embodiment. No amount of pressure will allow needle holder **94** or needle **28** to move forward since the front portion **100** of the needle holder is grounded or bottomed inside front **136** of nose **88**.

Blowout pressure is still a factor to be considered in connection with stopper **114**. Blowout pressure would be the pressure in chamber **130** produced by thumb force on cap **48** acting on the cross sectional area of stopper **114** which could overcome the holding force, causing stopper **114** to dislodge from opening **112** prematurely. The ratio of the maximum cross sectional area across the interior of variable chamber **130** to the maximum cross sectional area of stopper **142** exposed to pressure in chamber **130**, and the dislodging force necessary to dislodge stopper **144**, are selected so that the maximum expected thumb force on plunger **104** during an injection will not cause the stopper to blowout. Yet the stopper will still be dislodged by the dislodging force on the plunger once the front of stopper **114** contacts the retraction mechanism after the injection has ended. The ratio referred to is preferably not less than about two to one, or more preferably about three to one or more, whereby a force of about eighteen pounds on the plunger, for example, would produce a pressure generated force of only about nine or six pounds respectively, on the stopper, so that the stopper can be easily dislodged in advance of retraction at the end of the injection cycle but will not blowout during an injection. The smaller diameter stopper allows two or three times the thumb force to be used during the injection cycle than required to actually dislodge the stopper by direct application of force.

By reference to FIGS. **5–7**, the operation and further features of the alternate embodiment are discussed. The syringe is used in the normal manner until the plunger is depressed to the first position of FIG. **5** which is the end of the injection cycle. Stopper **114** has a forwardly extending end which has come into contact with head **102** of needle holder **94** to block fluid path **132**. Further depression of plunger **104** toward the position of FIG. **6** mostly or filly dislodges stopper **114** and begins spreading barrel **84** at the transition zone by sliding contact between head portion **106** and ramp **124**. Ramp **124** is a very small inwardly extending annular thickening of the wall of barrel **86** which can take many shapes or forms. For example, ramp **124** may be a small step **125** in the wall which continues vertically downward as indicated by the dotted line, which is somewhat exaggerated in FIG. **5**.

The barrel is flexible and is spread outwardly a slight amount to the position of FIG. **6** just prior to retraction. Here the mating surfaces **126, 128** are separated an amount which reduces the clamping force on the needle holder **94**. The spreading shown in FIG. **6** is greatly exaggerated for illus-

tration. It is estimated that an expansion of only about four thousandths of an inch is sufficient to release needle holder **94** from nose **88**. By slight further depression of the plunger from the position of FIG. **6** to the retracted position of FIG. **7**, retraction occurs when the retraction force applied by spring **96** exceeds the remaining holding force on needle holder **94**. Needle holder **94** then moves through opening **112** into cavity **108** along with a portion of spring **96**. The uncompressed length of spring **96** is designed to provide sufficient backward movement to withdraw an injection needle **28** fixed in front portion **94** and carry dislodged stopper **114** with it. At the same time, cap **42** enters opening **138** at the rear of a barrel extension **54** where the peripheral edge is closely confined in order to prevent tampering after retraction.

The location and configuration of ramp **124** is arranged to avoid cumulation of force required during the retraction sequence. Most of stopper **114** should be dislodged by thumb pressure on plunger **104** before significant resistance develops as angled surfaces **122** begin pushing outwardly on ramp **124**. The selection of the location of ramp **24** and the angle of the engaging surfaces make it possible to have a fairly smooth continuous force since the dislodging force continuously decreases as the sliding interface area **116, 118** between the plunger and the stopper is linearly decreased. Because ramp **124** is relatively very small, it is still possible to remove a stepped molding core from the rear of the outer body **84**. Alternately, ramp **124** can be the smaller diameter step **125** which avoids reentrant angles whereby resistance to removal of the molding core could occur. After retraction, the back of the plunger is unaccessible and there is no way to reach to stopper or the needle holder in order to reinstall them for re-use.

When used normally, syringe **10** may have a small amount of fluid remaining in the variable chamber in the second position shown in FIG. **2** which is, of course, greatly exaggerated in scale. This may amount to no more than a drop or a few drops of fluid in the remaining space above the retraction mechanism. When syringe **10** is fired by pushing down on end cap **48**, to the position of FIG. **3**, the expanding spring and rearwardly moving needle holder carry any remaining fluid up into retraction cavity **38**. Surface tension effects hold the tiny droplets in place along the walls of the plunger and no fluid escapes from nose **16**. The syringe is normally used to withdraw fluid from a vial. The fluid is injected into a patient followed by immediate retraction of the needle holder and needle in one step. No leakage of fluid from the nose is observed when the syringe is used to inject fluid into a patient.

It has been discovered, however, that if the needle is forcibly prevented from retracting after syringe **10** is "fired" by pushing down until plunger **48** enters opening **58**, the small amount of retained fluid from variable chamber **68** can flow into the nose in the space between the needle holder and nose. If the seal around the head of the needle holder is removed while the needle holder is being restrained from retracting, remaining fluid has time to move down into the nose, but it does not leak out from the opening in the front of the nose. Then if the needle holder is suddenly released and allowed to retract normally, it has been found that leakage of fluid from the opening in the front of the nose could be observed. This undesirable scenario was found to occur under the following circumstances. If the syringe is used to draw blood from the patient, the blood filled syringe is removed from the patient and the needle passed through a rubber septum in a sterile vial. The plunger is then depressed to discharge the patient's blood into the vial. Users expect to depress the plunger fully after the fluid is discharged to retract the needle. When the plunger is depressed fully to cause retraction, the needle cannot retract normally due to the fact it is frictionally held by the rubber septum of the vial. When the empty syringe is then withdrawn from the vial by pulling the needle out of the septum, it immediately retracts. Droplets of fluid were observed on the vial as soon as retraction took place.

Surprisingly, it was found that a small "puff" of air is the source of this problem. If the needle or needle holder is temporarily restrained and prevented from retracting in the normal manner, a brief puff of forwardly directed air is generated when the needle holder is finally allowed to retract. This puff of air was found to emerge from the front of the syringe causing retained fluid trapped around the needle holder to be blown out of the opening left in the nose when the needle holder retracts. It was discovered that if the hollow interior of the plunger is vented, preferably in the area of thumb cap, this condition does not occur and the fluid is entirely retained within the syringe body.

FIGS. **9** through **16** illustrate the syringe generally designated as syringe **10** with a modification on the end cap or thumb cap on the plunger to provide for venting of the hollow interior of the plunger which is the retraction cavity. Insofar as possible the original numbering of FIGS. **1–4** is retained with primes used to indicate differences.

Head **34'** of plunger **32'** is preferably slightly modified from plunger head **34** of FIG. **2** in the following respects. The elongated plunger has a longitudinally extending generally tubular wall **140** defining a hollow interior along the length of the plunger. The plunger has a head end **34'** in front and a rear end portion **142** with a thumb cap **48'** behind. The outer side of wall **140** at head end **34'** is sealingly surrounded with a resilient plunger seal member **36'** which is like a band with a pair of separated raised rings **144**. Plunger seal **36'** fits in a depression in the outer surface of wall **140** where it is securely held in position and prevented from longitudinal movement. Seal member **36'** is adapted to slide in sealed contact with a tubular wall when the plunger is moved within syringe barrel **14**. It is within contemplation of the invention to have a raised piston molded as part of the plastic plunger to serve as a plunger seal in place of a separate rubber plunger seal **36'**, although the rubber seal member is preferred.

Wall **140** at head end **34'** of the plunger **32'** has a reduced diameter front portion extending forward from seal member **36'** terminating at tip **40** at the front of plunger **32'**. Tip **40** defines the opening **41** which leads into the hollow interior **38**. The internal structure is as shown in FIG. **1**. The wall **140** behind tip **40** has a stepped inner side surface comprising a land having an inwardly facing surface and a larger diameter portion extending behind the land into the hollow interior. A separate dislodgeable stopper **42** is slidingly held within the reduced diameter front portion of plunger head **34'** by a holding force in excess of the fluid injection pressure force to be expected during use of the plunger in syringe barrel **14**. Stopper **42** has a back end portion comprising a land **46** and a reduced diameter front end portion extending forwardly beyond tip **40** a fixed distance to its front **146**. The fixed distance is the distance between front **146** and tip **40**.

As is seen in FIG. **1**, the outwardly facing surface **46** of dislodgeable stopper **42** is in sliding sealed engagement with the inwardly facing surface of land **44** in the plunger wall. These lands cooperate to apply a holding force to the stopper and seal hollow interior **38** of plunger **32'** from the expected amount of fluid injection pressure force generated in the

variable chamber **68** during an injection. The ratio of the effective area of variable chamber **68** to the area of stopper **42** exposed to fluid pressure is at least two to one and preferably three to one or more as previously indicated. This makes it possible to utilize lower holding forces without blowing out the stopper during an injection. The cooperating lands on the inside of the plunger head and the stopper have sufficient longitudinal length to allow dislodgeable stopper **42** to move the fixed distance between its initial extension at **146** and tip **40** in sliding response to forward movement of the plunger after front **146** of stopper **42** contacts a stop.

As indicated in FIGS. **1–3**, front **146** of the stopper **42** encounters head **72** of needle holder **22** which serves as a stop. The fluid opening in head **72** of needle holder **22** is preferably provided with some fine slots or grooves so that fluid can continually enter fluid path **70** as the plunger moves from the position of FIG. **1** to that of FIG. **2**. As the position of FIG. **2** is reached, the holding force on stopper **42** is reduced by substantial disengagement of the cooperating lands **44, 46** in preparation for dislodgement of the stopper, without unsealing the hollow interior/retraction chamber **38** within plunger **32'**. A notch **148** is preferably provided in the tip to prevent trapping fluid at the tip.

Thumb cap **48'** at the rear end portion **142** of plunger **32'** includes one or more channels **150** which receive vented air from hollow interior **38**. Thumb cap **48'** has an opening **152** for a closure **154** best seen in FIGS. **10** and **11**. Channels **150** are open at the top for ease of molding although closed channels could also be used.

FIG. **10** shows an enlarged top plan view illustrating the use of three channels **150** in combination with a preferred closure **154** installed in circular opening **152**. FIG. **11** best shows how the channels **150** receive vented air from hollow interior **38**. Closure **154** preferably has a stepped outer surface comprising a rear step **156** which rests in opening **152**, an intermediate step **158** which rests in an enlarged portion **160** of the inner side of wall **140** and a front step **162** which rests against inner surface **164** of wall **140**. In effect, these structures provide convenient seating for closure **154**. Steps **158** and **162** are conveniently provided in a downwardly depending skirt **166**.

Importantly, inner surface **164** everywhere there is a channel **150**, is provided with a longitudinally extending groove **168** in fluid communication with the hollow interior **38** and the channels **150**. Any convenient number may be chosen as the channels are easily molded into the end cap when it is formed. The longitudinally extending grooves **168** do not extend through the entirety of the wall **140** although they could. They are designed for ease of molding since they can formed in the mold that makes the plunger without using separate pins to form an opening. This is an important cost consideration in a multiple out high speed molding process. This structure is designed for preventing the user's thumb from obstructing the vent opening leading from the interior of the plunger thereby assuring that venting will take place.

Referring now to FIGS. **9** and **12**, it will be noted that opening **58** in the back end of barrel **14** includes slots **172** in fluid communication with the hollow interior of the plunger through one or more channels **150** so that when thumb cap **48'** is received in opening **58**, no seal is created by the thumb being in contact with opening **58** which might otherwise prevent air from venting. The outer periphery of thumb cap **48'** is closely received in opening **58** as the syringe is fired, to prevent reuse. Thumb cap **48'** is preferably sized in relation to barrel **14** such that opening **58** is simply an extension in a linear direction of the wall of barrel **14** rather than enlarged as shown. Finally, the interior surface **164** preferably has several annular constrictions **170** designed to catch the head of stopper **42** during its rearward travel. Since stopper **42** is preferably installed from the rear of the plunger before closure **154** is put in place, the constrictions **170** must allow stopper **42** to be forced through to the front.

A first alternative thumb cap and closure arrangement is illustrated in FIGS. **13** and **14**. In this embodiment, four channels **150** are provided in thumb cap **48"**. Closure **174** has four flat side portions **176** spaced around the periphery at 90° intervals, each in fluid communication with a channel **150**. A gap is created at each flat side between the flat sides **176** and the opening **152'** which are in fluid communication with interior **38** to create a flow passage for air from interior **38** through the gap along the flat side then into channel **150**. Annular groove **178** in closure **174** may be used to fluidly connect each of the flat areas **176** at the level of channels **150**. In addition to equalizing air flow, the annular groove allows venting of air regardless of the angular orientation of closure **174** with respect to thumb cap **48"**.

A second alternate embodiment has the same thumb cap **48"** with a modified closure **180**. Closure **180** has a head **182** which snugly fits within opening **152'** which is at the back of the plunger. Opening **152'** is only slightly larger than the interior of the plunger to provide a seat for the closure. Four undercut portions **186** are each in joint fluid communication with the interior **38** and one of the channels **150** to create a flow passage from the interior **38**. Closure **180** effectively seals the opening **152'** so that no fluid particles can escape from the opening. As in the previous embodiment, an annular groove **178** bridges each undercut portion opening into a corresponding channel **150** thereby tying the undercut portions together in fluid communication regardless of the angular orientation of the parts.

In operation, there are many advantages to the improved combination disclosed herein. The diameter of the stopper in both embodiments and the slidable retaning ring member in the first embodiment, in relation to the diameter across the fluid chamber, makes it possible to produce a syringe which withstands high blowout pressure. By minimizing the effective surface area exposed to the pressurized fluid during an injection, the syringe will withstand injection thumb force of around fifteen to eighteen pounds during injection and at the same time retract in response to as little as five to six pounds of force on the plunger once the injection fluid has been injected. Once the fluid has been injected, cumulation of force required to concurrently operate the retraction mechanism is avoided. First the stopper is moved back and then the needle holder is released. By constricting the diameter of the syringe near a transition zone where the nose begins, a constriction enables the needle holder to be smaller which in turn allows it to fit in a smaller opening with a smaller stopper in the retraction cavity of the hollow plunger.

A vacuum must be pulled in order to fill the syringe. The ring member or the needle holder, as the case may be, must seal the front nose of the syringe body because otherwise vacuum could be lost and fluid could enter the spring area and leak out the front. The hollow outer body and syringe plunger are preferably made from conventional plastic material used for syringes, which has some flexibility. The tolerances on the diameter of mating facing surfaces between the head of the needle holder and the barrel and between the stopper and head of the plunger are not critical in order to maintain a consistent holding and dislodging force. This is believed to be because increasing interference fit increases the frictional holding force only up to a point

and then the surrounding wall simply expands a small amount or the internal parts are compressed a small amount without a corresponding increase in the longitudinal force required to move the retainer member or plug member in the retraction direction. It is a desirable self correcting mechanism which is a cost and quality benefit in making the parts. It is believed that a plastic retainer member could be used and the same self limiting frictional holding force would be obtained.

In the best mode the stopper and the ring member are preferably made from a thermoplastic rubber material designated number 181-55 available from Advanced Elastomer Systems, 540 Maryville Centra Drive, St. Louis, Mo. and sold under the trade name Santoprene®. It is said to have a characteristic hardness around 55 on the Shore A durometer scale which allows for the right amount of resistance to compression, fluid resistance such that the material does not swell when in contact with most fluids, environmental stability allowing the friction and sealing properties to remain non-temperature sensitive, good property retention after aging and excellent property retention after sterilization by all accepted methods. The plunger seal around the head of the plunger is conventional.

The parts are few in number and easily mass produced. The alternate embodiment has the fewest number of separate parts of any tamperproof retractable syringe. The plunger has a one piece hollow outer body with a transition zone and a narrow nose portion. The internal diameter is stepped to greater diameters from front to back for molding around a non-collapsible core which can be extracted from the rear. The same is true for the plunger.

Assembly is greatly simplified and can be accomplished with high speed mechanized equipment. The needle holder and spring are installable from the rear of the barrel without the needle. In the first embodiment the retainer member is forced fit over the inner head of the needle holder and the assembly together with the uncompressed spring are pushed forward and held by sliding engagement of the cooperating inwardly and outwardly facing surfaces while compressing the spring. The front of the needle holder passes through an opening in the nose which makes it easy to install the needle from the front by conventional means. The alternate embodiment is installed the same way except that there is no separable retainer member around the head of the needle holder.

The narrow nose provides a particular advantage for mechanized assembly. The nose has a wall defining an elongated internal cavity which closely confines the spring and needle holder combination. During installation this cavity serves as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring. This solves an important assembly problem. If there is much lateral space in the nose around the spring, when the uncompressed spring is being compressed, it is a laterally unstable column which flexes sideways and bunches up causing a jam up. It might be added that rounded edges on the bottom of the slot directly below retainer **66** would further facilitate entry of the end of the spring.

The stopper is also installable from the rear of the plunger by pushing it forward until the cooperating lands are slidingly engaged. Then plug member **50** is force fit or otherwise fixed in the opening at the back of the plunger and the plunger is installed in the outer body. It is not necessary to try to pass the sharp needle through an elongated body with constricted openings where slight misalignment could cause hangups. The head of the needle holder simultaneously acts as a seal as well as a holding device such that no seal is required at the tip of the nose and no ultrasonic welding of separate parts is required.

There is no necessity for using internal locking teeth of any kind. No locking teeth are needed to hold the retraction mechanism or to lock the plunger after retraction. Locking teeth present difficult molding and quality control problems, tend to be temperature sensitive and tend to require a larger diameter barrel which increases premature blowout problems. In addition to the non-reusability provided by separation of the retainer ring from the head of the needle holder and dislodgement of the stopper, the plunger is not accessible after retraction because it is depressed within an opening at the back of the outer body. This additional tamperproof feature is provided in a one piece body without the necessity for hooking anything or twisting anything. The easily made and installed force fit plug at the back of the retraction cavity prevents access to the retracted components. The Federal government has rights in the invention under 35 U.S.C. §203. The Federal government has a nonexclusive, nontransferable irrevocable, paid up license to the invention as set forth in the priority documents.

I claim:

1. A syringe plunger handle assembly for use in a syringe barrel to inject fluid, comprising:

an elongated plunger formed with a longitudinally extending generally tubular wall defining a hollow interior along the length of the plunger, the plunger having a head end in front and a rear end portion with a thumb cap behind;

the outer side of the wall at the head end has a plunger seal adapted to slide in sealed contact with a tubular wall when the plunger is moved within a syringe barrel;

the wall at the head end of the plunger has a reduced diameter front portion extending forwardly beyond the plunger seal to a tip at the front of the plunger defining an opening within the front end portion leading into the hollow interior, the wall behind the tip having a stepped inner side surface comprising a land having an inwardly facing surface and a larger diameter portion extending behind the land into the hollow interior;

a separate dislodgeable stopper slidingly held within the reduced diameter front portion of the plunger head by a holding force in excess of an expected fluid injection pressure force during use of the plunger in a syringe barrel, the stopper having a back end portion comprising a land and a reduced diameter front end portion extending a fixed distance forwardly beyond the tip, the stopper land having an outwardly facing surface in sliding sealed engagement with the inwardly facing surface of the land in the plunger wall, said lands comprising cooperating lands which apply said holding force to the stopper and seal the hollow interior of the plunger from said expected fluid injection pressure force; and

the cooperating lands have sufficient length to allow the dislodgeable stopper to move said fixed distance back to the tip in sliding response to forward movement of the plunger after the front of the stopper contacts a stop, whereby said holding force is reduced by substantial disengagement of the cooperating lands in preparation for dislodgement of the stopper without unsealing the hollow interior of the plunger.

2. The syringe plunger handle assembly of claim **1** wherein a vent for the hollow interior is located at the rear end portion of the plunger.

3. The syringe plunger handle assembly of claim 2 wherein the thumb cap at the rear end portion of the plunger is provided with a channel which receives vented air from the hollow interior.

4. The syringe plunger handle assembly of claim 3 wherein said vent comprises at least one groove at the rear end portion of the plunger in fluid communication with said channel for venting the retraction cavity in the plunger.

5. The syringe plunger handle assembly of claim 1 wherein the thumb cap at the rear end portion of the plunger surrounds an opening suitable for installation of the dislodgeable stopper into the hollow interior and a closure for the opening in the thumb cap.

6. The syringe plunger handle assembly of claim 5 wherein at least one channel in the thumb cap receives vented air from the hollow interior.

7. The syringe plunger handle assembly of claim 6 wherein the closure has at least one cutaway side portion in joint fluid communication with the hollow interior and said channel to create a vent passage.

8. The syringe plunger handle assembly of claim 7 wherein the rear end portion of the plunger has an internal surface with at least one groove in fluid communication with the hollow interior and said at least one channel in the thumb cap.

9. The syringe plunger handle assembly of claim 5 wherein the closure has a headed portion fitted in the opening in the thumb cap and a skirted side containing an undercut configured to reside in fluid communication jointly with the hollow interior and at least one channel in the thumb cap to comprise at least one vent passage from the hollow interior.

10. A syringe plunger handle assembly and syringe barrel combination for use in a retractable syringe for injecting fluids, comprising:

a hollow syringe body having an elongated tubular wall comprising an elongated barrel portion having an open back end;

an elongated plunger disposed for reciprocation in sliding sealed contact with the barrel portion of the body, the plunger having a tubular wall defining a head portion in front, a back end portion carrying a thumb cap and hollow interior comprising a retraction cavity located between the head portion and thumb cap;

the thumb cap having an outer side adapted to reside in close association with the open back end of the plunger barrel when the plunger is nearly fully depressed; and

the plunger having a vent in fluid communication with the retraction cavity, to allow airflow from the retraction cavity.

11. The combination of claim 10 wherein the vent in fluid communication with the retraction cavity is located at the rear end portion of the plunger.

12. The combination of claim 11 wherein said vent is an opening in the wall of the plunger.

13. The combination of claim 11 wherein the thumb cap at the rear end portion of the plunger is provided with a channel which receives vented air from the retraction cavity.

14. The combination of claim 11 wherein the thumb cap at the rear end portion of the plunger is provided with a groove which receives vented air from the retraction cavity.

15. The combination of claim 13 wherein said vent comprises at least one groove at the rear end portion of the plunger in fluid communication with said channel for venting the retraction cavity in the plunger.

16. The combination of claim 15 wherein the back end portion of the barrel of the syringe body includes at least one slot which allows vented air to escape without being trapped by a user's thumb during retraction when the thumb cap is pressed down.

17. The combination of claim 10 wherein the thumb cap at the rear end portion of the plunger surrounds an opening in the thumb cap and has a closure for the opening in the thumb cap.

18. The combination of claim 17 wherein said vent is an opening in the wall of the plunger.

19. The combination of claim 17 wherein at least one channel in the thumb cap receives vented air from the retraction cavity.

20. The combination of claim 19 wherein the closure has at least one cutaway side portion in joint fluid communication with the retraction cavity and said channel to create a vent passage.

21. The combination of claim 20 wherein the rear end portion of the plunger has an internal surface with at least one groove in fluid communication with the retraction cavity and said at least one channel in the thumb cap.

22. The combination of claim 19 wherein the closure has a headed portion fitted in the opening in the thumb cap and a skirted side containing an undercut configured to reside in fluid communication jointly with the retraction cavity and at least one channel in the thumb cap to comprise at least one vent passage from the retraction cavity.

23. The combination of claim 19 wherein the back end portion of the barrel of the syringe body includes at least one slot which allows vented air to escape without being trapped during retraction when the thumb cap is pressed down.

24. A syringe plunger handle assembly for a retractable syringe, comprising:

a hollow syringe body having a longitudinally extending tubular wall comprising an elongated barrel portion having an open back end;

an elongated plunger having a head portion in front slidingly mounted for reciprocation within the hollow syringe body;

the plunger having a tubular wall defining the head portion in front, a rear end portion in back terminating in a thumb cap and a retraction cavity therein;

a dislodgeable stopper insertable through an opening in the thumb cap for installation within the head portion at the front of the plunger; and

a closure installable in the thumb cap wherein said end portion is vented to allow air flow to or from the retraction cavity.

25. A tamperproof retractable syringe structure designed for one use, comprising:

a hollow syringe body comprising a syringe barrel having an open back end, the barrel having a front end portion containing a retraction mechanism configured for operation by a plunger;

a plunger reciprocatably mounted in sliding sealed contact with the barrel, the plunger having a thumb cap at its back end for working the plunger relative to the barrel and a front end configured to operate the retraction mechanism;

the plunger having a tactile first position felt by a user pressing the thumb cap at the end of free travel of the plunger in the barrel when the plunger is moved forward to a stop, the plunger having a length relative to the length of the barrel whereby in the tactile first position of the plunger a portion of the plunger and the thumb cap extend behind the barrel for grasping in order to draw fluid into the barrel by partially withdrawing the plunger from the barrel;

the plunger having a retraction position obtained by pressing the thumb cap to move the plunger forward beyond the tactile first position and thereby operating the retraction mechanism and simultaneously lodging the thumb cap in the open back end of the barrel thereby rendering the thumb cap inaccessible for grasping.

26. The tamperproof retractable syringe of claim **25** wherein the thumb cap has a periphery slightly smaller than an opening at the back end of the barrel to frustrate efforts to remove the plunger from the barrel.

27. The tamperproof retractable syringe of claim **26** wherein the back end of the barrel does not resist entry of the thumb cap when the plunger is moved forward to the retraction position.

28. The tamperproof retractable syringe of claim **27** wherein entry of the thumb cap into the opening at the back end of the barrel is not accompanied by locking of the plunger in the barrel.

29. The tamperproof retractable syringe of claim **27** wherein the thumb cap reversibly enters the opening at the back end of the barrel.

30. The tamperproof retractable syringe of claim **26** wherein the opening at the back end of the barrel is adapted to receive the thumb cap freely without adding another component of retraction triggering force to overcome as the plunger is moved forward from the tactile first position to the retraction position.

31. The tamperproof retractable syringe of claim **26** wherein the opening at the back end of the barrel is configured as a stop which contacts the thumb cap after the thumb cap enters the opening to prevent further forward movement of the plunger.

32. The tamperproof retractable syringe of claim **31** wherein the back end of the barrel is radially enlarged relative to the barrel with a correspondingly larger opening at the back of the barrel and a correspondingly larger close fitting thumb cap than a syringe without said enlargement.

33. The tamperproof retractable syringe of claim **25** wherein the front end of the plunger has a closure which acts as the stop for the plunger when the plunger is moved forward to the tactile first position.

34. The tamperproof retractable syringe of claim **29** wherein the front end of the plunger has a closure which acts as the stop for the plunger when the plunger is moved forward to the tactile first position.

35. The tamperproof retractable syringe of claim **30** wherein the front end of the plunger has a closure which acts as the stop for the plunger when the plunger is moved forward to the tactile first position.

36. The tamperproof retractable syringe of claim **35** wherein the retraction mechanism comprises a needle holder held in an unretracted position by a removable ring member.

37. The tamperproof retractable syringe of claim **36** wherein the ring member is removed from the needle holder in response to movement of the plunger to the retraction position.

38. The tamperproof retractable syringe of claim **37** wherein the front end of the plunger has a closure which acts as the stop for the plunger when the plunger is moved forward to the tactile first position.

39. The tamperproof retractable syringe of claim **37** wherein the front end portion of the barrel comprises a nose portion of reduced diameter relative to the barrel, the nose portion principally containing the retraction mechanism.

40. The tamperproof syringe of claim **39** wherein the needle holder is grounded against forward movement in the nose of the syringe.

41. A tamperproof retractable syringe structure designed for one use, comprising:

a hollow syringe body having a barrel having an open back end and a nose portion in the front of the barrel;

a plunger operated retraction mechanism lodged in the nose portion of the barrel;

an elongated plunger handle disposed for reciprocation in the barrel, the plunger handle having a front portion slidingly sealing the barrel to form a variable fluid chamber above the retraction mechanism, the plunger having a thumb cap with a diameter slightly less than the diameter of the open back end;

the plunger having a tactile first pre-injection position which is felt by moving the plunger forward until it stops without operating the retraction mechanism, leaving a portion of the plunger handle and the thumb cap positioned a sufficient distance behind the barrel for gripping to partially withdraw the plunger when filling the syringe with fluid;

the plunger having a second position obtained by returning the plunger to the first pre-injection position to substantially empty the syringe then moving the plunger forward to a retraction position beyond the tactile first pre-injection position thereby operating the retraction mechanism and simultaneously lodging the thumb cap within the open back end of the barrel where it becomes inaccessible.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO : 6,090,077

DATED : July 18, 2000

INVENTOR(S) : Thomas J. Shaw

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 22, line 1
replace "Claim 35"
with --Claim 25--.

Signed and Sealed this

Twenty-fourth Day of April, 2001

Attest:

Nicholas P. Godici

NICHOLAS P. GODICI

Attesting Officer

Acting Director of the United States Patent and Trademark Office